

**THE PARTICIPANT EXPERIENCE IN COMMUNITY-DELIVERED DIABETES  
PREVENTION INTERVENTIONS: HEALTH-RELATED QUALITY OF LIFE AND  
DIRECT NONMEDICAL EXPENSES**

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Gerald Schafer, PhD

University of Pittsburgh, 2013

## **Abstract**

**Introduction:** Behavioral lifestyle interventions to prevent type 2 diabetes have been successful in reducing the risk of diabetes in clinical studies, while translational programs have demonstrated the ability to reduce diabetes risk factors in various community settings. However, there remain important questions about the impact of translational diabetes prevention programs on non-clinical factors like health-related quality of life (HRQoL) and the time and expenses faced by participants in these programs.

**Methods:** Data were collected from participants at three sites where the Group Lifestyle Balance (GLB) program, a behavior lifestyle intervention program adapted from the Diabetes Prevention Program (DPP) was delivered. Paper 1 reports on HRQoL among participants in a GLB intervention presented by diabetes educators at outpatient clinics. Paper 2 continues the investigation of HRQoL in a GLB program delivered through a medical clinic using group and DVD delivery modes. In Paper 3, direct nonmedical expenses for food and physical activity, as well as time in intervention-related activities are reported.

**Results:** Papers 1 and 2 showed that participants in a translational diabetes prevention interventions experienced modest improvements in HRQoL, measured by different assessment instruments. The findings in Paper 3 indicate that diabetes prevention participants can reduce clinical risk factors for type 2 diabetes without incurring additional expenses for food or physical activity, beyond expense of time due to involvement in activities related to the intervention.

**Public Health Significance:** Many individuals at elevated risk of type 2 diabetes consider themselves in good health. However, these individuals may face morbidities associated with type 2 diabetes unless they reduce their risk of the disease. Behavioral lifestyle intervention programs have demonstrated the ability to reduce diabetes risk. This dissertation suggests there may also be improvements in quality of life. This should help individuals at risk view prevention programs more positively, especially since participants need not incur significant additional out-of-pocket expenses. The summary message should be that you can reduce your risk of diabetes through moderate lifestyle intervention; you might feel a bit better; and it won't cost you much as long as you are willing to commit some time to the intervention.

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## ACRONYMS AND ABBREVIATIONS

ADA	American Diabetes Association
BDI II	Beck Depression Inventory II
BMI	Body Mass Index
CDC	United States Centers for Disease Control
CDC HRQoL	CDC-14 Healthy Days Measure
DPP	Diabetes Prevention Program
DPPOS	Diabetes Prevention Program Outcomes Study
DPRP	Diabetes Prevention Recognition Program
DPS	Finnish Diabetes Prevention Study
DPSC	Diabetes Prevention Support Center of the University of Pittsburgh
DTTAC	Diabetes Training and Technical Assistance Center at Emory University
EQ-5D	EuroQoL EQ-5D-3L
EQ-VAS	EuroQol Visual Analogue Score
GLB	Group Lifestyle Balance
HbA1C	Hemoglobin A1C
HDL	High Density Lipoprotein
HELP-PD	Healthy Lifestyle Partnerships to Prevent Diabetes

HRQoL	Health-Related Quality of Life
IDDM	Insulin Dependent Diabetes Mellitus
IFG	Impaired Fasting Glucose
IGT	Impaired Glucose Tolerance
LDL	Low Density Lipoprotein
LYG	Life Years Gained
MAQ	Modifiable Activity Questionnaire
MID	Minimally Important Difference
National DPP	National Diabetes Prevention Program
NCEP	National Cholesterol Education Program
NHANES	National Health and Nutrition Examination Survey
NHIS	National Health Interview Survey
NIDDK	National Institute of Diabetes, Digestive, and Kidney Disorders
NIDDM	Non-Insulin Dependent Diabetes Mellitus
OGTT	Oral Glucose Tolerance Test
QALY	Quality-Adjusted Life Years
QLI	Quality of Life Index
SF-36	36 Item Short Form Quality of Life Survey
SNAP	Supplemental Nutrition Assistance Program
USDA	United States Department of Agriculture
VAS	Visual Analogue Score
WHO	World Health Organization
YMCA	Young Men's Christian Association



## **1.0 INTRODUCTION**

### **1.1 RISK AND IMPACT OF DIABETES**

It is estimated that over 40% of American adults have hyperglycemic conditions, including type 2 diabetes, impaired fasting glucose (IFG), and/or impaired glucose tolerance (IGT) [1]. Although the criteria for the metabolic syndrome overlap with other hyperglycemic categories, more than 34% of adults aged 20 and over are also estimated to have the metabolic syndrome [2]. Additionally, the presence of prediabetes and the metabolic syndrome raise the risk of type 2 diabetes [3,4].

The physiologic impacts of diabetes are substantial, and include elevated risk of heart disease and stroke, blindness, kidney disease, nervous system damage, and amputations [5]. There are also under-acknowledged effects of diabetes on health-related quality of life (HRQoL) such as reduced mobility and pain or discomfort [6]. For many individuals with diabetes, the effects of these complications are some of the most immediate and debilitating consequences of the disease, dramatically affecting HRQoL.

In addition to the impact of diabetes on the individual, the economic impact of diabetes is considerable. In 2007, the total economic cost of all types of diabetes in the US was conservatively estimated at \$174 billion [7], including excess medical expenditures and the cost of reduced national productivity due to diabetes. Of that \$174 billion, the cost of type 1 diabetes

is estimated at \$14.9 billion or about 8.6% of the total [8]. This is in line with estimates that type 1 diabetes accounts for 5-10% of all diabetes cases [9], suggesting that the economic costs of type 1 diabetes and type 2 diabetes are roughly proportional to their prevalence in the population. In 2012, the estimated economic cost of diabetes had risen 41% to \$245 billion in constant 2007 dollars [10]. The health and economic impacts of diabetes are thus substantial, and diabetes makes a considerable contribution to the national disease burden on both individual and societal bases.

Using data from the National Health Interview Surveys (NHIS) from 1984 to 2000, it is estimated that for those born in 2000, the lifetime risk for diabetes is 32.8% for males and 38.5% for females [11], with 90-95% of the risk being for type 2 diabetes. Simulations of future rates and impacts forecast that both the numbers of people with type 2 diabetes and the costs associated with type 2 diabetes will continue to rise. The number of people with diabetes is predicted to increase from 23.7 million to 44.1 million in the 25 years between 2009 and 2034, with a near tripling of annual diabetes related spending (\$113 billion to \$336 billion) in constant 2007 dollars [12].

## **1.2 DIABETES PREVENTION**

To help mitigate the increasing public health burden of type 2 diabetes, the Diabetes Prevention Program (DPP) was tasked with determining whether it was possible to prevent or delay the onset of type 2 diabetes, using either a pharmacological or lifestyle approach. After an average follow-up of 2.8 years, the DPP clinical trial concluded that a structured behavioral lifestyle intervention, with targeted activity and dietary goals, was more effective than the anti-diabetes

drug metformin in reducing the risk for type 2 diabetes and the metabolic syndrome among those at elevated risk [13,14]. International studies have reported similar findings on the efficacy of moderate lifestyle change in reducing the risk of developing type 2 diabetes [15,16]. Effectiveness trials using modified versions of the original DPP curriculum have also been successful [17-50], establishing a solid scientific basis to assert that type 2 diabetes should to a great degree be considered a preventable condition. Given the DPP lifestyle results, which importantly were achieved without impacting hospitalization or mortality rates [13], interventions promoting moderate, healthy lifestyle changes should be considered a safe and effective public health prescription to prevent type 2 diabetes.

### **1.3 DIABETES AND HEALTH-RELATED QUALITY OF LIFE (HRQOL)**

While the Diabetes Prevention Program (DPP) and translational programs derived from it [17-50] have been successful in reducing risk factors for type 2 diabetes and/or the metabolic syndrome (risk factors include excess body weight, low HDL cholesterol, high triglycerides, high blood pressure, and elevated blood glucose [51]), there is increasing interest in using informative, non-clinical criteria when evaluating the impact of such programs. For example, in the DPP, HRQoL was assessed over the course of the investigation, with HRQoL scores related to physical condition and vitality showing improvements at clinical follow-up points, relative to baseline values [52]. This suggests a connection between diabetes risk factors and improvements in quality of life. It also points to potential benefits of weight loss, physical activity, and improved nutrition that extend beyond the reduction of clinical risk factors.

In addition to improvements in HRQoL reported in the DPP clinical trial [52], benefits to HRQoL have been reported in other lifestyle efficacy studies. The Swedish Björknäs study was an efficacy trial designed to improve cardiovascular disease risk factors using an intervention “broadly based” on the DPP [53]. Over a three year period, participants in the Björknäs study reported significant improvements in HRQoL physical components and in the EuroQol Visual Analog Scale (EQ-VAS) [54]. As well, in a consensus statement the International Diabetes Federation asserted that “early intervention and avoidance or delay of progression to Type 2 diabetes is of enormous benefit, both to patients in terms of increasing life expectancy and quality of life” [55]. The few efficacy studies that have examined HRQoL thus establish a basis to anticipate that participants in community translational interventions for preventing type 2 diabetes would likewise experience improvements in HRQoL. To this point, however, this has not been documented.

## **1.4 COSTS OF DIABETES PREVENTION**

While the economic costs to society for treating the morbidities and reduced productivity associated with diabetes are enormous [10], it is predicted that a national diabetes prevention program would produce nationwide savings [56]. These types of cost analyses take a broad perspective, reporting on overall costs or benefits to the economy or health care system. However, there are expenses related to diabetes and its prevention that impact the individual that have not been well documented. For example, there is the time commitment and out-of-pocket costs to participants related to involvement in a diabetes prevention program. When participating in a behavioral lifestyle intervention designed to prevent or delay type 2 diabetes

and the metabolic syndrome, participants are encouraged to modify their dietary and physical activity behaviors. This requires a commitment of time for program attendance and additional physical activity, as well as the potential for changes in out-of-pocket expenses related to food choices and transportation, as well as services or items to facilitate increased physical activity. Since food expenses have been shown to be the second most important factor behind taste in determining dietary choices [57], combined with a perception in the general population that healthy foods are more expensive than less healthy options (even if this is not necessarily true [58]), expenses, both for food and for other aspects of program involvement may thus be perceived as an obstacle to successful participation in a community diabetes prevention program, as well as for longer term maintenance of healthy lifestyle behaviors.

When considering the costs of a diabetes prevention intervention, several categories of expenses may be considered. Of most immediate interest from the participant's perspective are the direct nonmedical costs, those expenses which occur due to involvement in the program, but are not related to actual delivery of the program. These direct nonmedical costs include the value of time spent in the intervention; expenses on services, equipment, or clothing to facilitate physical activity; changes in food expenses and additional expenses for food preparation equipment; and transportation expenses. In the Diabetes Prevention Program (DPP), direct nonmedical costs for participants in the lifestyle intervention group were \$1445 higher over three years, compared to the placebo (placebo \$15,692, lifestyle \$17,137) [59]. The largest component contributing to the higher cost for the lifestyle group was the time-cost to the participants of the intervention visits—the actual value of time spent in the intervention that would have otherwise been spent elsewhere. Additional small contributing categories were exercise and health club

services, and transportation expenses. Food costs for the lifestyle intervention group were \$71 less over three years, compared with the placebo [59].

There is only one prior report on participant costs related to involvement in a diabetes prevention program based on the DPP. The Healthy Living Partnerships to Prevent Diabetes (HELP PD) found that expenses for lifestyle participants were \$955 (or \$1.31/day) greater than for the usual care participants over two years [60]. If this is confirmed in further translational studies, and by more comprehensive analyses, it would help reduce concerns that reducing diabetes risk factors through adopting a healthy lifestyle requires a significant financial outlay, beyond the time commitment necessary for successful participation in the intervention. Such a finding could be a helpful catalyst to reduce financial fears among many, particular those of lower socioeconomic status, which could contribute to a reluctance to participate in healthy lifestyle interventions from which they could derive substantial benefit.

These two topics, quality of life and cost, together constitute much of what a participant in a diabetes prevention intervention most directly experiences. Simply put, the answer to the questions “how do I feel and what’s it costing me?” have an enormous impact on a participant’s satisfaction with an intervention, and thus their willingness to remain enthusiastically engaged. Despite the importance of these issues, to this point there are limited reports addressing either quality of life issues or changes in expenses that participants face due to their involvement in diabetes prevention programs in the community.

## **1.5 STUDY GOALS**

Research findings have demonstrated that type 2 diabetes can be prevented, or the onset of diabetes can be delayed, using a behavioral lifestyle approach that includes moderate dietary, weight loss, and physical activity goals. Translational intervention programs have been effective in adapting successful clinical lifestyle approaches for community group delivery. In terms of expenses, the Diabetes Prevention Program (DPP) clinical trial reported that direct, nonmedical costs to participants were modest, with the major additional expense being that of the time spent participating in intervention activities. There have, however, been few reports on health-related quality of life among participants in translational diabetes prevention interventions. Additionally, direct nonmedical expenses accrued by participants in translational diabetes prevention intervention have not been thoroughly examined.

Based on the state of the literature, summarized above, this dissertation will analyze and describe the experience of participants in a modified DPP known as the Group Lifestyle Balance (GLB) program [18], a translational lifestyle intervention program that has been successfully implemented in a variety of community settings, [17,19-25]. The focus will be on the participant experience in terms of effects that are tangible and discernible from the participant's perspective. Specifically, it will include an evaluation of changes in health-related quality of life among participants over the course of the intervention, as well as an investigation of direct, nonmedical out-of-pocket expenses and time expenses related to program participation.

The following two questions will be examined in three papers that report findings from three separate GLB interventions:

1. *What changes in health-related quality of life (HRQoL) occur among participants over the course of involvement in a translational diabetes prevention program delivered in the community?*

This question will be addressed in papers 1 and 2. Paper 1 reports on changes in HRQoL among participants in a GLB program delivered by trained diabetes educators in three hospital outpatient settings. This was a single group, non-randomized prospective study, with clinical evaluations at baseline, four, six, and 12-months. At each clinical visit, participants completed the CDC HRQoL–14 Healthy Days Measure (CDC HRQoL) [61]. This assessment tool consists of four core questions about general health and the number of unhealthy days during the past 30 days, followed by ten questions about recent levels of pain, depression, anxiety, sleeplessness, and vitality; and the cause, duration, and severity of any current limitation of activity. As well as reporting changes in HRQoL over the course of the intervention, additional analyses will be presented that compare HRQoL categories with attendance of GLB session, as well as achievement of weight loss and physical activity goals. It is hypothesized that modest improvements in HRQoL will occur among participants in the GLB program, compared to baseline.

Paper 2 contains an analysis of HRQoL changes in a second GLB intervention, a pilot project evaluating two modes of delivering the intervention program: a traditional group setting in a primary care clinic, and via DVD with telephone support. The goal was not to compare delivery modes, but rather to demonstrate the effectiveness of the DVD as an alternative to the established and successful group mode. In this non-randomized study design, participant HRQoL was assessed by the EuroQol EQ-5D-3L™. This instrument consists of two components: the EQ-5D, on which participants indicated their current level of functioning in



each of five dimensions (mobility, self-care, usual activities, pain and discomfort, anxiety and depression) by choosing one of three levels, equivalent to “none,” “moderate,” and “extreme.” These five dimensions can be converted into a single index score that summarizes overall HRQoL. Also part of the EuroQol EQ-5D-3L is the Visual Analogue Scale (VAS) which consists of a figure resembling a thermometer marked 0-100. Participants use this device to report their current health state, with zero representing the “worst imaginable health state” and 100 represents the “best imaginable health state.” It is hypothesized GLB program participants, regardless of delivery mode, will report increases in some HRQoL components, compared to baseline values.

Taken together, these two papers will provide an accounting of HRQoL among participants in translational diabetes prevention interventions, using a variety of assessment tools and analytical approaches. These findings will add to the existing literature about type 2 diabetes prevention and quality of life in community-delivered diabetes prevention programs based on the DPP behavioral lifestyle intervention.

2. *What changes in direct nonmedical out-of-pocket expenses do participants face while taking part in a translational diabetes prevention program? Are there associations between attainment of the program goals for weight loss, physical activity, or session attendance, and the amount spent or types of expenditures made by participants?*

Paper 3 will present results from participants in a GLB intervention delivered through a network of community centers with a high proportion of older adults. At the clinical baseline and follow-up visits, participants completed a multi-question expenses survey that captured the time and out-of-pocket expenses related to their involvement in the intervention. The survey was

compiled for this investigation from various sources, including the National Health and Nutrition Examination Survey (NHANES) Consumer Behavior Questionnaire [62]. In addition to the survey, participants were requested to save household food purchase receipts for two-week periods, providing a supplementary itemized record of food purchase amounts at grocery and other food stores, take-out food, and restaurants. It is hypothesized that participants will experience little change in direct nonmedical expenses over the course of the intervention, compared with baseline. Additionally, some associations between clinical or behavioral outcomes and money or time expenses will emerge.

These findings will help strengthen the diabetes intervention and prevention literature regarding the direct expense to participants in prevention efforts. As well, they will provide values of typical participant expenses that can be used to inform perspective participants as to the time and expense commitments associated with involvement in a translational diabetes prevention program.

## **2.0    HYPERGLYCEMIC CONDITIONS: DIABETES AND THE METABOLIC SYNDROME**

Three main types of diabetes are generally recognized, conditions where for various reasons blood glucose is elevated above a normal level: type 1 diabetes and gestational diabetes will be briefly described; type 2 diabetes will be addressed in greater depth as it is the focus of this dissertation.

### **2.1    TYPE 1 DIABETES**

Previously referred to as juvenile or childhood diabetes, and alternatively known as insulin dependent diabetes mellitus (IDDM), type 1 diabetes is an autoimmune disease where insulin producing beta cells in the pancreas become damaged and are unable to produce sufficient insulin [63]. This results in elevated blood glucose levels. Although diabetes statistics at times lump type 1 and type 2 diabetes together (in economic analyses, for example [10]), type 1 diabetes accounts for 5-10% of all diabetes cases [9], with the incidence of type 1 diabetes increasing in children and youth by about 3% per year [64]. A summary of the characteristics of type 1 and type 2 diabetes is presented in Table 2.1.

**Table 2.1 Characteristics of Type 1 and Type 2 Diabetes**

Characteristics	Type 1	Type 2
Age	6 months to young adulthood	Usually pubertal (or later)
Clinical presentation	Most often acute, rapid	Variable: from slow, mild (often insidious) to severe
Insulin dependence	Permanent, total, severe	Uncommon, but insulin required when oral hypoglycemic agents fail
Insulin sensitivity	Normal	Decreased
Frequency (% of all diabetes in young people)	Usually 90%+	Most countries <10% (Japan ~80%)
Association with Obesity	No	Strong

Derived from [65,66]

The long-term vascular complications of type 1 diabetes include retinopathy, nephropathy, neuropathy, and macrovascular disease. Diabetic retinopathy results in visual impairment and blindness; diabetic nephropathy leads to renal failure and hypertension; diabetic neuropathy leads to pain, muscle weakness and autonomic dysfunction; diabetic macrovascular disease raises the risk of cardiac disease, peripheral vascular disease and stroke [67]. It will be noted in the next section that these complications and morbidities are also experienced by those with type 2 diabetes. This is not unexpected, for although the etiologies of type 1 and type 2 diabetes are different, they both result in persistently elevated blood glucose which negatively impacts organs and organ systems.

## **2.2 TYPE 2 DIABETES**

### **2.2.1 Background and Epidemiology**

Type 2 diabetes was formerly known as adult onset diabetes, or non-insulin dependent diabetes mellitus (NIDDM). This chronic, lifestyle-related disease is characterized by an elevated level of plasma glucose. The state of elevated plasma glucose arises from a relative, not an absolute insulin deficiency, as pancreas insulin production does continue. Rates of type 2 diabetes have increased steadily over recent years to the point where it has been labeled an epidemic due to its current and anticipated impact on global health [68]. The prevalence of diabetes diagnoses in the US rose from 5.1% in 1988-1994 to 7.7% in 2005-2006 [1], and it is estimated that in 2010, 25.6 million or 11.3% of those aged 20 and older had diabetes [5]. Of these numbers, 90-95% of the cases are type 2 diabetes [69]. Globally, the World Health Organization (WHO) estimates that approximately 312 million people have type 2 diabetes [70], with this number projected to rise to 380 million by 2025 [71].

### **2.2.2 Diagnostic Criteria**

The 2012 American Diabetes Association criteria for the diagnosis of type 2 diabetes are: [72]

A1C  $\geq 6.5\%$ . The test should be performed in a laboratory using a method that is NGSP certified and standardized to the DCCT assay.\*

OR

FPG  $\geq 126$  mg/dl (7.0 mmol/l). Fasting is defined as no caloric intake for at least 8h.\*

OR

2-h plasma glucose  $\geq 200$  mg/dl (11.1 mmol/l) during an OGTT. The test should be performed as described by the World Health Organization, using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water.\*

OR

In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose  $\geq 200$  mg/dl (11.1 mmol/l).

\* In the absence of unequivocal hyperglycemia, criteria 1–3 should be confirmed by repeat testing.

### **2.2.3 Risk Factors**

Risk factors for type 2 diabetes include: age > 45 years; first-degree relative with type 2 diabetes; African-American, Hispanic, Asian, Pacific Islander, or Native-American ethnicity; history of gestational diabetes or delivery of infant weighing  $\geq 9$  lbs; polycystic ovary syndrome; overweight, especially abdominal obesity; cardiovascular disease; hypertension; dyslipidemia, or other metabolic syndrome components [73]. While age, family history, race, and ethnicity are clearly non-modifiable, the other factors, particularly obesity, are very much amenable to intervention in order to reduce the risk of type 2 diabetes.

With regard to weight, the Nurses' Health Study showed that, after adjustment for age and body mass index at age 18 years, women who had a weight gain of 5.0 to 7.9 kg between the of age 18 and the year 1976 had a relative risk of 1.9 (95% CI, 1.5 to 2.3) of getting diabetes, compared with women with stable weight (those who gained or lost less than 5 kg between age 18 years and 1976). For women who gained 8.0 to 10.9 kg, the relative risk rose to 2.7 (CI, 2.1 to 3.3). A risk reduction for diabetes of 50% or more was noted among women who lost more than 5.0 kg after adjustment for age and body mass index at age 18 years [74].

Physical activity is also related to the development of diabetes, with Kriska et al [75] showing that the incidence rate of diabetes incidence was lower among more active individuals compared with less active individuals in all body mass index groups for both men and women, excepting the middle body mass index tertile in men. The relation between physical activity and

diabetes incidence remained statistically significant ( $p < 0.01$ ) when adjusted for age and body in women [75].

#### **2.2.4 Pathologies in Type 2 Diabetes**

Continuing cellular exposure to high plasma glucose levels in type 2 diabetes leads to serious microvascular damage and debilitating morbidities, including retinopathy, neuropathy, and nephropathy, as well as damage to larger blood vessels, which raises the risk of heart attack and stroke [76,77]. Among adults aged 20-74, the most common cause of new blindness is diabetic retinopathy, with >60% of patients with type 2 diabetes acquiring retinopathy within 20 years of diagnosis [78]. Nephropathy associated with type 2 diabetes is the leading cause of end stage renal disease in the developed world, with 40% of patients starting dialysis in 1998 in the US having diabetic nephropathy [79].

### **2.3 GESTATIONAL DIABETES**

Gestational diabetes mellitus is a state of elevated blood glucose that emerges during pregnancy among women without a prior diagnosis of diabetes [80]. In a review, rates of gestational diabetes varied dramatically by geography and racial/ethnic background, with a prevalence of less than 2% in Sweden, where there is universal screening; rising to 4.9% to 12.8% in high risk Native American, Hispanic, and Asian Americans; and as high as 17% among Indian women in Australia [81]. Given the large variability in reported rates, as well as conflicting guidelines and screening protocols, it is a controversial diagnosis [82]. In 2008, the US Preventive Services

Task Force revisited the issue of screening for gestational diabetes and confirmed the 2003 finding that there was insufficient evidence to recommend for or against routine screening or treatment of gestational diabetes [83].

Even though blood glucose often returns to normal following pregnancy, gestational diabetes remains a risk factor for the development of type 2 diabetes [80]. Women with a history of gestational diabetes have a 35 to 60 percent chance of developing diabetes in the next 10 to 20 years [5], higher than the 38.5% lifetime risk of acquiring diabetes for all women [11].

## **2.4 PREDIABETES**

### **2.4.1 Definition, Diagnosis Criteria, and Epidemiology**

Prediabetes is a state of elevated risk for developing type 2 diabetes that is characterized by blood glucose indicators that are elevated, but lower than the cut point for a diagnosis of diabetes [84]. Prediabetes is defined by The Expert Committee on Diagnosis and Classification of Diabetes Mellitus as the presence of impaired fasting glucose (IFG) (fasting plasma glucose 100-125 mg/dl), impaired glucose tolerance (IGT) (2-hour values in the oral glucose tolerance test (OGTT) of 140 mg/dl to 199 mg/dl), or an HbA1C value of 5.7% to 6.4% [72,85,86 ].

In 2005, based on fasting plasma glucose and HbA1C levels, 35% of U.S. adults aged 20 years or older had prediabetes, with a rate of 50% in adults aged 65 years or older. This yields an estimate in the U.S. population in 2010 of 79 million American adults aged 20 years or older with prediabetes [5]. Among those with prediabetes, from 5-10% convert to diabetes each year,



and, although it may take many years, up to 70% of individuals with IGT and/or IFG develop diabetes [87].

### **2.4.2 Pathophysiology**

Prediabetes arises due to a failure of body cells to respond to insulin, a condition known as insulin resistance. When pancreatic beta cells can no longer produce enough insulin to overcome insulin resistance, blood glucose levels rise, first reaching prediabetes levels, and often increasing further to diabetic levels [88]. There is evidence that cellular insulin resistance and compensatory pancreatic insulin secretion increase occurs years before the actual development of type 2 diabetes [89], and that during the pre-diabetic phase, beta cell function decreases [90].

### **2.4.3 Pathologies in Prediabetes**

While prediabetes does not have a unique ICD-9 code, diagnosable only in the category of “other abnormal glucose” [91], there are nevertheless pathologies and complications, usually associated with diabetes, that often emerge during the pre-diabetic state. Prediabetes has been associated with early nephropathy and chronic kidney disease [92,93] as well as a variety of neuropathies [84]. Although a long-recognized complication of diabetes, retinopathy has also been associated with prediabetes and the metabolic syndrome. In the Diabetes Prevention Program (DPP), 7.9% of participants without diabetes showed signs of retinopathy [94]. Using fundus photography, lesions consistent with retinopathy were found in 12% of individuals in a study of Pima Indians with IGT, none of whom had diabetes at the time of the previous oral glucose tolerance test (OGTT) [95]. The Swedish NANSY-Eye Study also reported the presence of retinopathy before

the diagnosis of type 2 diabetes [96]. Insulin resistance, characteristic of prediabetes is associated with an increased risk of cardiovascular disease [97]. There is, however, evidence that any increased risk of cardiovascular disease may be due to the presence of multiple cardiometabolic risk factors, and that isolated hyperglycemia may not be a unique risk cardiovascular disease factor [98]. The relationship between prediabetes and ischemic stroke, as well, is inconsistent, [99]. Taken together, however, these findings support the notion that prediabetes may not be merely be a state of elevated risk of diabetes, but that in fact it has concomitant morbidities, particularly neuropathy, nephropathy, and retinopathy.

## **2.5 THE METABOLIC SYNDROME**

### **2.5.1 Definition, Diagnosis Criteria, and Epidemiology**

The metabolic syndrome is defined by the National Cholesterol Education Program (NCEP) Adult Treatment Panel 3 criteria as a clustering of abdominal obesity, atherogenic dyslipidemia, hypertension, and insulin resistance. Diagnostically, the metabolic syndrome is determined by the presence of three or more of the following five conditions: [100]

1. elevated triglycerides ( $\geq 150$  mg/dl)
2. low HDL cholesterol ( $< 40$  mg/dl for men,  $< 50$  mg/dl for women)
3. increased waist circumference ( $> 102$  cm for men,  $> 88$  cm for women)
4. blood pressure  $\geq 130/85$  mm Hg (or on treatment for hypertension)
5. elevated fasting plasma glucose ( $\geq 100$  mg/dl).

Analysis of National Health and Nutrition Examination Survey (NHANES) data from 2003-2006 found that about 34% of US adults met the criteria for the metabolic syndrome [2], and over 40% of the population have either type 2 diabetes or prediabetes [1,101].

The above criteria, dating from 2001, have been widely used in the US, however, other international organizations have proposed alternatives, particularly with regard to the cut-off point for waist circumference, and whether or not central adiposity should be an obligatory component [102]. As well, there is question as to whether the metabolic system as a single factor has any more predictive or descriptive value than its individual components [103]. Nevertheless, the metabolic syndrome, as defined above, continues to be used by many researchers as a diagnostic and predictive criterion.

### **2.5.2 The Metabolic Syndrome as a Predictor of Type 2 Diabetes and Cardiovascular Disease**

When compared to those with no metabolic syndrome components, those with the three or more components of the metabolic syndrome were found to have an adjusted hazard ratio for developing type 2 diabetes of 22.50 (95% CI: 11.21-45.19), with abdominal obesity and hyperglycemia most strongly linked to an outcome of diabetes [3]. In review, Ford [104] concluded that, using the NCEP criteria, those with the metabolic syndrome had a relative risk for cardiovascular disease of 1.65 (1.38-1.99) and 2.99 (1.96-4.57) for type 2 diabetes.

## **2.6 THE COSTS OF TYPE 2 DIABETES**

In 2007, the total cost burden of diabetes and its complications in America was estimated at \$174 billion [7]. This amount consists of \$116 billion in excess medical costs and \$58 billion in lost national productivity, including disability, loss of work, and premature mortality [7]. People with diabetes have medical expenditures 2.3 times higher than those without diabetes, and about \$1 of every \$10 spent in the US is attributed to the cost of diabetes, along with 1 in every 5 healthcare dollars being spent caring on an individual with diabetes [7]. By 2012, the estimated cost of all diabetes-related expenses had risen by 41% to \$245 billion: consisting of \$176 billion in direct medical costs, and \$69 billion in reduced productivity [10].

Further analyses, conducted as part of the Novo Nordisk National Changing Diabetes Program, estimated that nearly \$218 billion was spent on diabetes and prediabetes in the US in 2007. This included \$14.9 billion for type 1 diabetes and \$159.5 billion for diagnosed type 2 diabetes [105], \$18 billion for undiagnosed diabetes [106], \$25 billion for prediabetes [107], and \$636 million for diagnosed gestational diabetes [108].

Simulations of the future rates and impact of diabetes project that both the numbers of people with diabetes and the related costs will continue to rise, with an increase from 23.7 million to 44.1 million in the number of people with diabetes in the 25 years between 2009 and 2034, and a near tripling of annual diabetes related spending (\$113 billion to \$336 billion) in constant 2007 dollars [12]. Clearly, then, hyperglycemic conditions constitute an enormous economic burden, one that can potentially be attenuated through programs designed to prevent type 2 diabetes.

## **2.7 PREVENTION OF TYPE 2 DIABETES AND THE METABOLIC SYNDROME**

Given the prevalence of diabetes and the personal and economic burden it imposes, efforts have been made to identify the best ways of preventing type 2 diabetes or delaying its onset. Initially, this consisted of randomized clinical trials, followed by translational interventions in the community. As individuals with prediabetes and the metabolic syndrome are at elevated risk for more serious conditions, including diabetes and cardiovascular disease, prevention efforts typically focus on the reduction of diabetes risk factors. One approach is the use of behavioral lifestyle programs, including those adapted from the Diabetes Prevention Program (DPP) lifestyle intervention [13,14]. The focus of these programs is weight loss, a reduction of fat in the diet, and increased physical activity.

### **2.7.1 Clinical Trials for the Prevention of Type 2 Diabetes**

The first major study investigating the possibility of diabetes prevention through lifestyle intervention was the Swedish Malmö study [109]. Enrolling 181 individuals with impaired glucose tolerance (IGT), the study protocol included a six-month period of supervised physical training and six months of dietary education. In 1991, six-year follow-up results were published, indicating that it was possible to induce and maintain lifestyle changes in those with IGT, resulting in improvement in glucose tolerance as well as reducing blood pressure and lipids.

Other international studies also demonstrated that lifestyle modification is an effective approach to prevent or delay diabetes. Results from the Da Qing study in China showed that participants with IGT randomized to one of three active treatment groups, consisting of diet only, exercise only, or diet plus exercise, had diabetes risk reductions of 31%, 46%, and 42%,

respectively, when compared with the control group [16]. The Finnish Diabetes Prevention Study (DPS) reported in 2001 that among participants with IGT, the risk of type 2 diabetes was reduced by 58% in the lifestyle intervention group, compared to the control group [15]. Follow-up of DPS participants over 13 years shows a continuing reduction in diabetes risk in the intervention group, when compared to the control group [110].

In 2002, results from the Diabetes Prevention Program (DPP) in the US were published. In this trial, 3,234 participants without diabetes were randomized to one of three study arms: placebo, metformin (850 mg, 2 times per day), or lifestyle modification, with minimum goals of 150 minutes per week of moderate physical activity and 7% weight loss. After almost three years of follow-up, the lifestyle and metformin groups were found to have diabetes risk reductions of 58% and 31% respectively, relative to the placebo group [13]. As well as reducing the incidence of type 2 diabetes, the DPP lifestyle participants had a 41% reduction in the incidence of the metabolic syndrome, compared with the placebo [14]. The DPP lifestyle intervention was also more effective than the placebo or metformin in reducing cardiovascular risk factors and the need for pharmacologic therapy to achieve target blood chemistry values [111]. Ongoing follow-up of DPP participants as part of the Diabetes Prevention Program Outcomes Study (DPPOS) confirms that participants in the lifestyle arm of the original DPP intervention continue to benefit despite partial weight regain, with diabetes incidence rates among lifestyle participants 34% lower in the lifestyle group, and 18% lower in the metformin group, compared with the placebo after 10 years [112]. These DPP results, in conjunction with the earlier international findings, have established the clinical efficacy of type 2 diabetes prevention based on moderate lifestyle intervention.

Building on the studies described above, the Indian Diabetes Prevention Programme [113] randomized individuals of Asian Indian background into one of four groups: 1. Control; 2. Lifestyle modification; 3. Metformin; 4. Lifestyle plus metformin. The participants had IGT at baseline and were younger, less overweight, and more insulin resistant than the previously mentioned investigations. Lifestyle modification consisted of advice on a healthy diet, specifically, a reduction in total calories, refined carbohydrates, and fats, as well as the avoidance of sugar and inclusion of fiber rich foods. After a median follow period of 30 months, the risk of diabetes was reduced by 28.5% ( $p=0.018$ ) in the lifestyle group and 26.4% ( $p=0.029$ ) in the metformin group, compared to the controls. The combination of metformin and lifestyle conferred no additional risk reduction beyond the components taken separately.

### **2.7.2 Translational Research Studies**

Since publication of the DPP results, research efforts have focused on translating the clinical findings of the DPP in a variety of settings. Typically, the DPP curriculum is adapted for group presentation, rather than the one-on-one delivery used in the DPP, and the content of the original 16 sessions may be condensed and offered in fewer sessions.

Several groups have developed DPP-based curriculums and approaches. Of particular interest is the Group Lifestyle Balance (GLB) program, developed by the Diabetes Prevention Support Center (DPSC) at the University of Pittsburgh and used in this investigation. The GLB program consists of 12 weekly core group sessions, with bi-weekly and then monthly follow-up sessions. This year-long program is designed to be delivered by trained group leaders who have medical or educational credentials, and has been successfully implemented in a variety of

settings, including a primary care practice, out-patient diabetes education clinics, fitness centers, a church, and an underserved urban community [17-25,33]. A DVD adaptation of the GLB program has also been shown to be effective [24]. Other translational approaches include the use of supervised lay community health workers as group leaders in order to increase the pool of potential leaders [44-46,50,114], and various electronic media approaches [48,49,115].

### **2.7.3 The National Diabetes Prevention Program**

Building on the success of clinical and translational programs for preventing type 2 diabetes, in 2010 the US Congress authorized the establishment of the National Diabetes Prevention Program (National DPP) by the Centers for Disease Control (CDC) in order to increase the availability of low cost diabetes prevention intervention programs [116]. This program focuses on four core elements: training, recognition programs, intervention sites, and health marketing.

A variety of training programs are currently available, including through the Diabetes Prevention Support Center (DPSC) at the University of Pittsburgh and the Diabetes Training and Technical Assistance Center (DTTAC) at Emory University. The Diabetes Prevention Recognition Program (DPRP) is a key component of the National DPP. The DPRP maintains a record of and grants recognition to programs that have demonstrated an ability to effectively deliver the lifestyle change intervention and ensure quality and consistency, using an approved curriculum. Additionally, through recognized delivery sites, the National DPP facilitates the provision of diabetes prevention programming in sites around the country, and is helping to facilitate strategies and approaches to increase referrals and participation in these programs [116].



### **3.0 HEALTH-RELATED QUALITY OF LIFE IN CHRONIC LIFESTYLE-RELATED DISEASES**

The effectiveness of behavioral lifestyle intervention programs in preventing diabetes and the metabolic syndrome among those at elevated risk is thus well established in the clinical research setting, with such programs having been shown to favorably modify clinical measures and reduce the risk of diabetes. In a translation setting, adaptations of the Diabetes Prevention Program (DPP) lifestyle intervention have been shown to be effective in lowering risk factors for diabetes and cardiovascular disease. However, there is also increasing recognition of the value of assessing non-clinical outcomes in human-subjects research, known as humanistic outcomes. Quality of life is one important non-clinical outcome that has a substantial effect on the experience and perceptions of a participant in a biomedical intervention. The perspective of the participant is particularly important in community interventions, where protocol adherence and attendance remain challenging issues affecting individual and program success.

It has been found that the presence of elevated blood glucose is associated with a reduction in health-related quality of life (HRQoL) in both individuals with diabetes [6,117-119] and those without [120,121] and also in the metabolic syndrome [122]. Thus, there is a basis to consider HRQoL among individuals at elevated risk of diabetes, and how participation in a diabetes prevention program may impact HRQoL.

Previous reports indicate that HRQoL generally improves with physical activity [123] and this is specifically true among individuals with prediabetes [124]. The association, however, between HRQoL and weight loss is not consistent [125].

The Centers for Disease Control (CDC) defines health-related quality of life as “an individual’s or group’s perceived physical and mental health over time” [126]. There is increasing acceptance that traditional, direct measures of population health, including disease rates and life expectancy, do not provide a complete picture of the health of a population. Recognizing this, the Healthy People 2020 initiative included HRQoL and Well Being as a new topic area that will be monitored, with a focus on improving HRQoL, in addition to treating or preventing the underlying pathology [127].

### **3.1 ASSESSMENT OF HEALTH-RELATED QUALITY OF LIFE**

There are multiple instruments that have been developed for assessing health-related quality of life (HRQoL). Typically, these instruments ask a series of questions about recent or current mental and physical health, with the participant responding in a quantitative manner by selecting from categories that are provided, or by giving their own numerical answers, for example: number of days or times in the past month a certain condition has existed. HRQoL surveys may be generic, or designed for use within a specific condition (such as diabetes [128]).

A description of three widely used generic HRQoL assessment tools follows. The 36 item short form (SF-36) was developed in the early 1990s for use in the Medical Outcomes Study, a project to identify reasons for variation in hospital patient outcomes [129]. It has been extensively used in clinical practice, research, health policy evaluations, and population surveys,

and was used in the Diabetes Prevention Program (DPP) to assess HRQoL [52]. The 36 questions assess eight concepts: 1. Physical functioning; 2. Role limitations due to physical problems; 3. Social functioning; 4. Bodily pain; 5. General mental health; 6. Role limitations due to emotional problems; 7. Vitality; 8. General health perceptions [130].

The EuroQol Group ([www.euroqol.org](http://www.euroqol.org)) is an international network of researchers which focuses on measuring health status. In 1990s, the EQ-5D three-level version (EQ-5D-3L) was introduced [131]. It consists of two parts: the EQ-5D and the Visual Analogue Scale (VAS). The EQ-5D includes five questions about mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, for which participants specify their current level of problems in each of the five dimensions by choosing one of three options equivalent to “none,” “moderate,” and “extreme.” The VAS is a figure that resembles a thermometer on which participants indicate how “good” or “bad” their health is that day, with 0 representing the “worst imaginable health state” and 100 representing the “best imaginable health state.” It has been shown that the EQ-5D can suffer from a ceiling effect when administered to the general population or among patients with a mild condition, leading to issues in measuring small changes in health, accordingly, the EuroQol group has developed and tested a five level version of the EQ-5D, known as the EQ-5D-5L [132].

Developed by CDC, the CDC HRQoL–14 Healthy Days Measure (CDC HRQoL) assesses self-reported health [61]. It consists of four core questions about general health and the number of unhealthy days during the past 30 days, followed by ten questions about recent levels of pain, depression, anxiety, sleeplessness, or vitality, and the cause, duration, and severity of any current activity limitation.

### **3.2 HEALTH-RELATED QUALITY OF LIFE (HRQOL) IN CARDIOVASCULAR DISEASE PREVENTION**

It is instructive to consider quality of life among participants in behavioral or lifestyle programs for the prevention or treatment of cardiovascular disease, as many of the clinical and behavioral objectives of such programs, including increased physical activity, dietary changes, and weight loss, are similar to those utilized in diabetes prevention interventions.

The ADDITION Netherlands program tested the effect of pharmacological and lifestyle treatment to reduce cardiovascular risk factors in patients with type 2 diabetes. After one year, the intensified intervention and routine treatment groups both had similar improvements in general health, vitality, and mental health, as well as unexpected declines in social functioning, assessed by the SF-36 [133]. A systematic review of lifestyle interventions to reduce the burden of atrial fibrillation concluded that these programs improve HRQoL, with benefits concentrated in scores related to physical functioning [134]. Among patients with systolic heart failure, a randomized controlled trial of a home-based program of moderate aerobic and resistance activities resulted in significant improvement in HRQoL, using the Minnesota Living With Heart Failure Questionnaire, compared with the control group [135]. A primary prevention telemedicine program promoting lifestyle change (consisting of self-monitoring and physical activity) in patients at risk for cardiovascular disease reported significant improvement in physical health on the WHO QoL-Short, with no change in other areas of quality of life [136]. Likewise, participants in a secondary prevention program for heart disease, which included modification of behavioral risk factors, including physical activity, nutrition, and weight management, also had HRQoL improvements in the mental component summary, social functioning, and role-emotional of the SF-36 [137].

The findings from these studies are not entirely consistent. There is, however, evidence that behavioral programs for preventing primary or recurring cardiovascular disease outcomes also have a positive effect on HRQoL, measured in a variety of settings and with differing HRQoL assessment instruments.

### **3.3 HEALTH-RELATED QUALITY OF LIFE (HRQOL) IN OBESITY AND WEIGHT LOSS**

There has been considerable interest in the relationship between HRQoL and obesity, and what impact weight loss has on HRQoL. It is generally accepted that obesity is associated with decreased HRQoL. Using survey data from the 2000 Medical Expenditure Panel survey, Jia and Lubetkin [138] showed that HRQoL decreased with increasing obesity, even in those without chronic diseases linked with obesity, using the Physical Components Summary (PCS-12) and Mental Components Summary (MCS-12) of the SF-36, as well as the EuroQol EQ-5D, and VAS. Similar findings come from England, where, using the EQ-5D for HRQoL assessment, HRQoL was found to peak at a BMI of 26.0 in men and 24.5 in women, declining both as BMI increased and decreased [139].

As obesity is uniformly associated with decreased HRQoL, it is plausible that weight loss would result in increased HRQoL. The findings on this topic, however, are not consistent, and there remains disagreement over the relative contribution of obesity versus poor fitness that is responsible for the reductions in HRQoL found in obese individuals. In 2005, Maciejewski et al [125] published a structured review of the relationship between HRQoL and weight loss in randomized controlled weight loss trials, concluding that HRQoL outcomes did not consistently

improve with weight loss. However, the overall quality of the trials was judged to be poor, and the lack of standardized HRQoL measures limited firm conclusions. It should be noted that this review looked at weight loss using a variety of techniques, including surgical, pharmacological, and behavioral.

Since the 2005 review, behavioral weight loss studies have reported generally positive associations between weight loss and HRQoL. Williamson et al [140] found that among overweight or obese adults with type 2 diabetes, those randomized to an intensive lifestyle intervention experienced a significantly greater increase in HRQoL than those in a diabetes support and education group, using the PCS-12 and Beck Depression Inventory II (BDI-II). Importantly, they found that those with the lowest baseline HRQoL experience the greatest improvement in HRQoL over the course of the intervention. In a 12-week workplace weight loss program, Bruno et al [141] showed that both in-person and internet-based participants had improved HRQoL, assessed with the CDC-14. There was also a relationship between weight-related clinical outcomes and HRQoL, consistent with the findings of Ross et al [142] who found weight loss contributed individually to improvement in seven of nine domains of the SF-36.

### **3.4 HEALTH-RELATED QUALITY OF LIFE (HRQOL) AND PHYSICAL ACTIVITY**

The relationship between physical activity and HRQoL remains unclear, with contradictory findings in the literature. Among individuals with prediabetes, Taylor et al [124] concluded that those who achieve physical activity guidelines have higher physical and mental HRQoL than those who are inactive, using the RAND-12 Health Status Inventory. In a regression model, Jie

et al [143] found that physical activity and nutrition were the strongest predictors of improved HRQoL, measured by the Spanish language version of the Quality of Life Index-Diabetes Version (QLI), among Hispanic adults with diabetes. As well, Bize et al [123] in a review of the topic concluded that cross-sectional data are consistent in showing a positive relationship between physical activity and HRQoL. However, Bize also acknowledges that there is limited evidence from controlled trials and cohort studies. In an attempt to elucidate this issue, Ross et al [142] provided a six month lifestyle intervention to 298 obese women. Using hierarchical regression to control for baseline BMI, physical fitness, and HRQoL domain, they determined that the only HRQoL domain to which physical fitness contributed beyond the effects of weight loss was to the Physical Functioning domain. Weight loss was significantly associated with improvements in most of the other domains. Thus, while the best-designed study to specifically address relationships between physical activity, weight loss, and HRQoL concluded that weight loss was the primary contributor to improved HRQoL in lifestyle intervention studies, a randomized controlled trial may be required to settle the issue.

### **3.5 HEALTH-RELATED QUALITY OF LIFE (HRQOL) IN PROGRAMS FOR PREVENTING TYPE 2 DIABETES AND THE METABOLIC SYNDROME**

While associations between individual components of lifestyle-based diabetes prevention programs and HRQoL have been investigated, particularly increased physical activity and weight loss, there are few reports on HRQoL in community translational diabetes prevention settings. As behavioral lifestyle interventions for diabetes prevention are multi-pronged endeavors,

consisting of dietary, weight loss, and physical activity goals, as well as a group session component, it is tempting to attempt to identify which of the various intervention components is most associated with or responsible for any change in HRQoL that occurs over the course of the intervention.

Ackermann et al [144] looked at changes in HRQoL using the SF-36 among participants in the Diabetes Prevention Program (DPP) and found that weight loss was independently associated with improvements in HRQoL, in both the lifestyle and metformin arms of the study. As the DPP was a large study, statistical power was sufficient to detect significant differences in HRQoL between the treatment arms, although these differences were considered “clinically small.” It was also noted that changes in physical function on the PCS-36 scale were greater in persons with more severe obesity at baseline, as well as estimating that weight loss in the range of 5-10 kg was necessary to result in a “clinically meaningful” increase in overall health status [144] (“clinically meaningful” was not defined).

Reporting on the DPP clinical trial at a mean follow-up of 3.2 years, Florez et al [52] found that during the first year of the intervention, the lifestyle group experienced a significant increase in physical function, general health, and vitality scores, relative to the metformin and placebo groups. The improvement reached the level of minimally important difference (MID), defined as the smallest differences that is perceived as beneficial or deleterious [145], in this case, 3%. There was a decline in these scores in all groups over the subsequent follow-up years, but the lifestyle group retained a significant benefit relative to the placebo. In the lifestyle group, weight loss was identified as being the most important factor associated with the improvements in HRQoL [52].



In South Korea, Oh et al [146] conducted a six-month lifestyle modification intervention in women with the metabolic syndrome. Fifty-two women with a mean age of 62.7 years were randomized to intervention or control groups. The lifestyle modification program was offered over the course of six months, and consisted of a total of 60 sessions. During the first three months, sessions occurred three times per week, followed by twice per week during the final three-month maintenance period. Components of the intervention included health monitoring, counseling, health education, supervised exercise, and diet. The control group was given an educational booklet. At baseline, the mean fasting plasma glucose in the intervention group was 106.6 mg/dl and 103.6 mg/dl for the control group. Although data was not provided on the prevalence of prediabetes in the participants, the mean values suggest that many of the participants had a fasting plasma level in the prediabetes range (fasting plasma glucose 100-125 mg/dl [86]). Participants were assessed at three, six, and 12 months. In addition to clinical assessments, they completed the SF-36 to evaluate HRQoL. Significant improvements occurred in the following variables in the intervention group: Vitality and General Health at three and six months; Physical Function and Mental Health at six months. These improvements in HRQoL, however, did not maintain significance at 12 months. For the control group, these markers were negative or unchanged through six months. To summarize, Oh and colleagues [146] demonstrated improvements in several HRQoL variables through six months of regular contact with a study group of middle aged women with the metabolic syndrome, many of whom likely had prediabetes.

In a nine-month intervention for individuals at risk for type 2 diabetes, defined as the presence of prediabetes or the metabolic syndrome without diabetes, Cezaretto et al [147] randomized 177 participants to either an intensive interdisciplinary intervention or a traditional

control group. The intensive interdisciplinary intervention consisted of three medical visits where participants were given written guidelines on dietary change and physical activity (the traditional treatment that was also given to the control group) as well as an individual appointment with a dietitian and two-hour group sessions: offered four times per month for the first month, one to two sessions during the second month, and once per month through the ninth month. Members of the intensive group also were given print materials that included hints for living a healthier lifestyle and telephone calls between sessions. The baseline evaluation included clinical and laboratory measures, as well as questionnaires, with a follow-up evaluation at nine months. Participants also completed the SF-36 survey to assess HRQoL. At the nine month visit, participants in the intensive intervention had significant improvements in most of the HRQoL domains as well as the summary measures. There were also improvements in HRQoL in the control group. However, when compared with changes in the control group, the intensive intervention group only had greater improvement in the physical function and role-emotional domains. Vitality was found to have a significant inverse correlation with BMI.

In addition to these reports, there are several ongoing community diabetes prevention programs that anticipate reporting HRQoL results in future years. These include: Yates et al in the UK [148], Vlaar et al in the Netherlands [149], Colagiuri et al in Sydney, Australia [150], and Williams et al in the Fit Body and Soul, a faith-based adaptation of the DPP [32].

## **4.0 HEALTH-RELATED QUALITY OF LIFE IN TWO TRANSLATIONAL DIABETES PREVENTION EFFORTS (PAPERS 1 & 2)**

### **4.1 OVERVIEW OF THE GROUP LIFESTYLE BALANCE PROGRAM**

The Group Lifestyle Balance Program (GLB) is based on the successful Diabetes Prevention Program (DPP) which demonstrated that the risk of type 2 diabetes can be reduced through moderate lifestyle intervention [13]. There were, however, significant personnel and financial resources that the DPP, as a funded clinical trial, had available that are not typically present in public health intervention settings. Accordingly, the GLB was developed and tested by the Diabetes Prevention Support Center (DPSC) at the University of Pittsburgh as a translational adaptation of the DPP curriculum for group delivery in the community [18]. Table 4.1 presents a comparison of the DPP and GLB interventions.

The GLB intervention consists of 12 core sessions, typically delivered over the course of 12 weeks, presented either in groups or via DVD [24] with trained coach support. These core sessions are followed by 4 bi-weekly core sessions, transitioning to six monthly maintenance support sessions, continuing for approximately one year. Session content alternates between the three main content strands of a healthy lifestyle: eating, physical activity, and behavioral. Program materials and support are available through the DPSC ([www.diabetesprevention.pitt.edu](http://www.diabetesprevention.pitt.edu)).

GLB group leaders or preventionists generally have a background in a health-related field, and participate in a two-day training program offered by the DPSC. The training includes a review of the DPP intervention and findings, as well as thorough coverage of each of the intervention sessions.

**Table 4.1 Comparison of DPP Lifestyle Intervention to GLB Intervention Program**

**Fundamental aspects of DPP and GLB interventions**

- **Goal:** 7% weight loss and increase physical activity to 150 minutes/week
- Safe and appropriate intervention that incorporates nutrition, physical activity, and behavior change
- Intervention delivered by appropriately trained group leader
- Strong focus on use of self-monitoring tools with feedback
- Use of problem-solving techniques to address barriers to healthy eating and physical activity

**Specific adaptations to DPP intervention**

<b>DPP intervention</b>	<b>Modified GLB</b>
■ 16 core sessions delivered over 24 weeks with monthly follow-up	■ 12 weekly core sessions delivered over 12–15 weeks, with bi-weekly and monthly follow-up
■ Individual counseling	■ Group classes
■ Focus on food pyramid	■ Primary focus on healthy food choices
■ Initial emphasis on fat intake	■ Initial emphasis on fat intake and calories
■ Pedometer introduced during maintenance phase	■ Pedometer introduced during core sessions
■ Use of lifestyle toolbox	■ Use of inexpensive food samples and incentives
■ Lifestyle coach training conducted by DPP LRC	■ Prevention training conducted by DPSC faculty via 2-day workshop
■ Ongoing support for implementation provided by LRC	■ Ongoing support for implementation provided by DPSC

(DPP, Diabetes Prevention Program; DPSC, Diabetes Prevention Support Center; GLB, Group Lifestyle Balance; LRC, Lifestyle Resource Core)

From Kramer et al [18]

## **4.2 HEALTH-RELATED QUALITY OF LIFE (HRQOL) IN A COMMUNITY DIABETES PREVENTION PROGRAM (PAPER 1, APPENDIX A)**

In order to further address the question of HRQoL changes among participants in a community diabetes prevention program, there was an opportunity to analyze the results from a Group Lifestyle Balance (GLB) intervention, delivered in Western Pennsylvania and reported in Paper 1. (See Appendix A for full paper)

### **4.2.1 Overview**

This GLB intervention was conducted at three community hospital and outpatient clinic sites operated by the University of Pittsburgh Medical Center. The three sites included rural, suburban, and urban settings. In keeping with a real-world translational approach, the study design was single-group and nonrandomized. All of the GLB group leaders were diabetes educators, and all group leaders attended a 2-day GLB training workshop presented by the Diabetes Prevention Support Center (DPSC).

### **4.2.2 Eligibility**

Individuals in the community were eligible based on the following:

Eligibility Criteria:

- Nondiabetic individuals age 25 years or older **AND**
- BMI  $\geq 25$  kg/m<sup>2</sup> **AND**
- Presence of prediabetes (fasting plasma glucose 100-125 mg/dl) **AND/OR**
- Presence of the metabolic syndrome [100]

#### Exclusionary Criteria:

- Pregnant or lactating
- Failure to obtain physician approval to participate
- Plans to leave area before end of the study

#### **4.2.3 Recruitment**

Local primary care physicians and endocrinologists were contacted by email and postal mail with information about the study. Additional educational information was presented at visits to local healthcare clinics. The expectation was that the care providers would refer patients meeting the eligibility criteria. Program fliers were posted in the community and advertising was placed in local newspapers. After a 10-month recruitment period, 121 referrals were received, with 95 individuals meeting the eligibility criteria and 81 enrolling in the program.

#### **4.2.4 HRQoL Assessment Tool**

The CDC HRQoL–14 Healthy Days Measure (CDC HRQoL) was used for assessment of self-reported health [61]. It consists of four core questions about general health and the number of unhealthy days during the past 30 days, followed by ten questions about recent pain, depression, anxiety, sleeplessness, or vitality; and the cause, duration, and severity of any current activity limitation. The CDC HRQoL was completed at each assessment visit (baseline, six, and 12 months).

#### **4.2.5 Laboratory and Anthropometric Measures**

Local medical laboratories provided fasting (minimum of 8 hours) analysis of total cholesterol, HDL cholesterol, LDL cholesterol, triglycerides and fasting plasma glucose. Blood pressure was measured while seated, following a five minute rest period. Shoeless height and weight measurements were recorded along with waist circumference midway between the lower rib margin and iliac crest. All anthropometric measures were conducted twice, with the average values used in the analyses.

#### **4.2.6 Baseline Demographics**

Table 4.2 details baseline demographic characteristics. The participants were primarily female (88%) and white (96%), with an average age of 52.9 years. Most had completed college or had some college or technical school training.

**Table 4.2 Baseline Demographic Characteristics of Participants (Paper 1)**

	Male (n = 10) n (%)	Female (n = 71) n (%)	Total (n = 81) n (%)
Age, y <sup>a</sup>	52.3 (39-66)	53.0 (26-80)	52.9 (26-80)
White	9 (90)	69 (97)	78 (96)
Employed full-time/part-time	6 (60)	54 (76)	60 (74)
Education			
High school/GED	1 (10)	17 (24)	18 (22)
Some college/technical school	5 (50)	32 (45)	37 (46)
College graduate	1 (10)	17 (24)	18 (22)
Graduate degree	3 (30)	5 (7)	8 (10)
Smoking	1 (10)	6 (8)	7 (9)
Family history			
Diabetes	4 (40)	38 (54)	42 (52)
Heart disease	2 (20)	49 (69)	51 (63)
Prediabetes (glucose, 100-125 mg/dL)	6 (7)	34 (42)	40 (49)
<sup>a</sup> Mean (range).			

Kramer et al. [21]

#### **4.2.7 Paper 1 Abstract (See Appendix A for full paper)**

##### **Health-Related Quality of Life in a Community Diabetes Prevention Program**

**Purpose:** To evaluate health-related quality of life among participants in a community-based diabetes prevention program, delivered by trained diabetes educators.

**Methods:** HRQoL was evaluated for 81 participants in a presentation of the Group Lifestyle Balance program at three outpatient clinics in Western Pennsylvania, using the CDC HRQoL–14 Healthy Days Measure (CDC HRQoL). Change in HRQoL over the course of the intervention



was assessed. Additionally, associations between HRQoL and GLB attendance, weight loss, and physical activity goals were investigated.

**Results:** Post-intervention, participants reported an increase in the number of “healthy days” and days when they “felt very healthy and full of energy,” (11.0% to 14.9%,  $p=0.02$ ) compared with baseline, as well as a decrease in the number of days when they reported they didn’t get enough rest or sleep (10.7% to 6.3%,  $p=0.002$ ). Participants for whom the number of unhealthy days in the past month was less than 14 were significantly more likely to have attended 50% or more of the sessions than those who reported 14 or more unhealthy days ( $p=0.001$ ).

**Conclusions:** Individuals with prediabetes and/or the metabolic syndrome who participated in a community diabetes prevention intervention experienced positive changes in several HRQoL domains over the course of the program. In addition, HRQoL was associated with participant success in achieving some of the program goals. These results demonstrate that benefits to community diabetes prevention programs extend beyond improvement in the physiological parameters typically measured. This finding broadens the scope and value of community lifestyle intervention programs for diabetes prevention. (See Appendix A for full paper)

The findings presented in Paper 1 demonstrate that participants in a diabetes prevention intervention can experience improvements in their health-related quality of life. In another GLB intervention, the program was delivered using DVDs as an alternative to the standard group delivery, as well as using a different HRQoL assessment instrument. These results are reported in Paper 2.

### **4.3 HEALTH-RELATED QUALITY OF LIFE (HRQOL) IN A DIABETES PREVENTION INTERVENTION PRESENTED IN GROUPS AND VIA DVD (PAPER 2, SEE APPENDIX B)**

Paper 2 (See Appendix B for full paper) presents an analysis of HRQoL among participants in the Group Lifestyle Program (GLB), delivered in a traditional group setting and via DVD with long distance telephone support. Participants completed the EuroQol EQ-5D-3L™ and EuroQol VAS HRQoL assessment instruments at baseline, and post intervention (three months), six-month, and 12-month clinical visits. Analysis of HRQoL is presented for all participants taken together, and separately for those in the group and DVD delivery sections.

#### **4.3.1 Overview**

This GLB intervention was delivered in a California primary care practice. Participants chose their preferred program delivery mode for the GLB intervention: DVD or group delivery. Those selecting DVD were instructed to view one session per week. DVD participants received a telephone call from the DPSC each week to review program details, collect weight and activity levels, and answer questions.

#### **4.3.2 Eligibility**

Individuals in the community were eligible based on the following:

Eligibility Criteria:

- Nondiabetic practice patients age 18 years or older **AND**

- BMI  $\geq 25$  kg/m<sup>2</sup> **AND**
- Presence of prediabetes (fasting plasma glucose 100-125 mg/dl) **AND/OR**
- Presence of the metabolic syndrome [100] **AND**
- Ability to read and understand English

Exclusionary Criteria:

- Failure to obtain physician approval to participate

#### **4.3.3 Recruitment**

Patients meeting eligibility criteria were referred by their health care provider. Baseline demographic data collected included age, race/ethnicity, employment status, and highest education level attained.

#### **4.3.4 HRQoL Assessment Tool**

The EQ-5D-3L™, used in this study, is a self-administered questionnaire designed to assess HRQoL, consisting of two parts: the EQ-5D and the Visual Analogue Scale (VAS). For the EQ-5D, participants indicated their current degree of problem in each of five dimensions by choosing one of three levels, equivalent to “none,” “moderate,” and “extreme.” Results from these five dimensions were converted into a single summary index value using an algorithm available from EuroQol ([www.euroqol.com](http://www.euroqol.com)), based on American rankings of the relative health impact of possible EQ-5D responses [151]. Index scores range from 0 to 1, with higher values indicating better HRQoL.

#### **4.3.5 Laboratory and Anthropometric Measures**

Local medical laboratories provided fasting (minimum of 8 hours) analysis of total cholesterol, HDL cholesterol, LDL cholesterol, triglycerides and fasting plasma glucose. Blood pressure was measured while seated, following a five minute rest period. Shoeless height and weight measurements were recorded along with waist circumference midway between the lower rib margin and iliac crest. All anthropometric measurements were taken twice, with the average values used in data analyses.

#### **4.3.6 Baseline Demographics**

Table 4.3 details baseline demographic characteristics. The participants were primarily female (71%) and white (83%), with an average age of 59.7 years. Over half had completed college or had some college or technical school training.

**Table 4.3 Baseline Demographic Characteristics (Paper 2)**

	Total n=48 n (%)
Age mean (range)	59.7 (22-87)
Female	34 (71)
White	40 (83)
Employed full/part time	25 (52)
Highest Education	
Some High School or Lower	3 (6)
High School/GED	10 (21)
Some college/tech school	16 (33)
College graduate	11 (23)
Graduate degree	8 (17)
Smoker	1 (2)
Family History	
Diabetes	25 (52)
Heart Disease	24 (50)

Kramer et al [24]

#### **4.3.7 Paper 2 Abstract (See Appendix B for full paper)**

##### **Health-Related Quality of Life (HRQoL) in a Diabetes Prevention Intervention Presented in Groups and Via DVD**

**Purpose:** To evaluate HRQoL among participants in a community-based diabetes prevention program, presented in group delivery format and via DVD.

**Methods:** HRQoL was evaluated for 48 participants (22 DVD, 26 Group) in a presentation of the Group Lifestyle Balance program through a California medical clinic, using the EQ-5D-3L™. Change in HRQoL over the course of the intervention was assessed with particular focus on participants who had below-average HRQoL levels at baseline.

**Results:** No significant changes occurred in the EQ-5D index scores at three, six, and 12 months, compared to baseline. This finding remained the same when participants in the two delivery methods were combined, and when they were analyzed separately. However, when limiting the analyses to those participants whose baseline EQ-5D index scores were below the US average value of 0.87 [152] and who attended the three month assessment visit (n=27), there was an increase in the HRQoL index score at three months of borderline significance (p=0.07). Over the course of the intervention, there were significant increases in the median Visual Analogue Scale (VAS) scores of study participants from baseline to every clinical follow-up point, with the VAS score increasing to 80 at the three- (p<0.010) and six-month (p=0.03) assessment visits, and reaching 85 at 12 months (p=0.02). These increases remained significant when analyzing DVD or group delivery modes individually.

**Conclusions:** Among individuals with prediabetes and/or the metabolic syndrome who participated in a community diabetes prevention intervention, there were indications of improvement in HRQoL over the course of the intervention, particularly among those with below-average HRQoL at baseline. That the study group as whole did not experience improvements in HRQoL as measured by the EQ-5D index score may be because many individuals with prediabetes and/or the metabolic syndrome are not yet experiencing a substantial impact in their quality of life, at least as measured by the three levels of the EQ-5D (no, some, or extreme). However, the 0-100 continuum of the VAS scale allowed the capture of modest improvements in HRQoL. (See Appendix B for full paper)

## **5.0 COST ISSUES IN DIABETES PREVENTION**

In order to successfully participate in a behavioral lifestyle intervention for diabetes prevention, significant commitments are required by the participant: time commitments which include the actual time spent in intervention sessions; time to travel to the sessions, participation; and time spent in physical activity; financial commitments for the expense of getting to the intervention sessions, the potential of lost work hours during session, as well as additional expenses for items like activity cloths or services. Although the benefits of preventing diabetes are enormous, it can take years to realize the benefits, while the expenses are more immediate. It is thus important that these expenses be acknowledged and evaluated, as they may pose a real or imagined obstacle for some potential participants.

### **5.1 COST-EFFECTIVENESS OF DIABETES PREVENTION**

The cost-effectiveness of diabetes prevention intervention programs is generally accepted. In a review of 56 studies, Li et al [153] concluded that “a large majority” of interventions recommended by the American Diabetes Association (ADA) are cost-effective overall. In particular, intensive lifestyle interventions for prevention of type 2 diabetes among individuals with impaired glucose tolerance (IGT) were deemed “very cost-effective” compared with



standard lifestyle recommendations. “Very cost-effective” was defined as  $\leq \$25,000$  per life year gained (LYG) or quality-adjusted life year (QALY).

A ten-year intention to treat evaluation of cost-effectiveness in the Diabetes Prevention Program (DPP) found that the lifestyle intervention was “cost-effective” and metformin was “marginally cost-effective,” compared to the placebo. The lifestyle intervention resulted in a cost of \$10,037 per QALY. With most published cost-effectiveness ratios falling between \$10,000 and \$50,000 per QALY, the DPP lifestyle intervention for diabetes prevention was determined to be cost-effective relative to other interventions and treatments [154]. Further analyses of adherent DPP participants in the Diabetes Prevention Program Outcomes Study (DPPOS), defined as achieving and maintaining a 5% reduction in initial body weight, yielded a relative risk reduction for type 2 diabetes of 49.4%. Over 10 years, lifestyle intervention was deemed cost-effective compared with the placebo group [155].

Taking into account the costs and impact of a community Group Lifestyle Balance (GLB) intervention, Smith et al [156] calculated the cost per QALY gained as \$3,420. Anderson [157] concluded that among those over 65 years of age, 75% of whom have prediabetes or diabetes, lifestyle interventions are highly cost-effective and possibly cost-saving to a health care insurance payer. Using findings from the Finnish Diabetes Prevention Study, simulated in a Swedish setting, Lindgren et al estimated that a diabetes prevention program would be cost saving for 60 year olds, with a cost of 2,363€ (~\$3074) per QALY [158]. Zhuo et al [56] estimated that a nationwide community lifestyle intervention program to prevent type 2 diabetes would prevent or delay about 885,000 cases of diabetes within 25 years, resulting in savings of 5.7 billion dollars. In the Indian Diabetes Prevention Programme, Ramachandran et al [159]

reported that lifestyle modification was cost-effective, with \$1,052 estimated as the cost to prevent one case of diabetes.

Clearly, then, there is strong evidence in support of the overall cost-effectiveness of diabetes prevention interventions. However, some analysis suggests otherwise, with Irvine et al [160] estimating the cost-effectiveness of group sessions to prevent type 2 diabetes as being beyond generally accepted values (usually ~\$20,000/QALY), while admitting a large degree of uncertainty.

Part of cost-effectiveness calculation is the actual expense of the intervention. Both the GLB program and an adaptation of the DPP curriculum for group delivery in YMCA facilities have reported on the expenses of delivering these programs in the community. For the GLB intervention, the cost of program delivery, including monthly follow-up visits, materials, and supplies, has been estimated to be in the range of \$165 to \$320, \$2731 per center, and \$20 per pound lost [18,21,161]. Similar cost estimates (\$275 to \$325) were reported for the YMCA DPP-based intervention [162].

## **5.2 PERSPECTIVE IN COST-EFFECTIVENESS ANALYSES**

The economic cost of a preventive intervention, such as diabetes prevention, can be considered from a number of perspectives. A panel convened by the US Public Health Service issued a consensus statement in 1996 deeming the societal perspective as the “reference case, where benefits, harms, and costs to all parties are accounted for” [163]. This is the most comprehensive perspective, as it includes health impacts such as longer life, better function, and unwanted side effects, as well as medical and resource costs and the time of patients and caregiver. Other

perspectives will necessarily exclude potential costs or benefits as they are not within the purview of the interested party. For example, it may be that an employer is interested only in the costs and benefits that directly affect a business, including employer implementation and insurance costs, as well as employee productivity, and have no concern for costs paid by the employees [164]. By not considering employee cost, a cost-effectiveness analysis may conclude benefit to the employer, when if employee costs were included as part of an analysis from a societal perspective, the results would be different. While it is tempting to assume that the societal perspective would be universally used, this is not the case, in part due to the difficulty in assessing the whole spectrum of costs and benefits which accrue.

While cost-effectiveness analyses have generally shown benefit for diabetes prevention screening and intervention, there is an important aspect of expenses related to diabetes prevention, not reviewed yet, that has received little attention in the published literature, that of the personal economic costs faced by a participant due to their involvement in the program. These costs are detailed by Songer et al [165] in a comprehensive consideration of the societal costs related to type 2 diabetes prevention in children, and include the following direct nonmedical expenses faced by participants, and thus of interest here:

1. Time: Any time spent on intervention-related activities is time that would otherwise be spent on a different activity. This time expense is known as opportunity cost.
2. Food Costs: Diabetes prevention interventions include dietary goals that usually require that the participant to make changes in food purchase behavior, including the potential for increased expenses.
3. Physical Activity Costs: The cost of equipment and clothing used for physical activity, as well as any gym membership, and club or personal trainer expenses.

4. Travel Costs: The expense for transportation to and from intervention sessions as well as clinical visits. This may be the expense of using a personal vehicle, public transportation, or taxi.

### **5.3 PARTICIPANT COSTS IN THE DIABETES PREVENTION PROGRAM (DPP)**

The DPP collected and reported on multiple aspects of cost, looking specifically at 1). direct medical costs—the actual expenditure for medical services; 2). direct nonmedical costs—those out-of-pocket expenses arising from the intervention, including participant travel and food expenses, as well as the opportunity cost of session attendance and time spent in physical activity; and 3). indirect costs—the costs for time lost from work as a result of participating in the DPP [59]. Of particular interest for the purposes of this investigation are the direct nonmedical costs in community diabetes prevention programs, as these expenses may function as perceived barriers to greater community participation in such programs.

#### **5.3.1 Assessment of Nonmedical Costs in the DPP**

Estimates of direct nonmedical participant costs in the DPP were made in a number of ways [59]. For the opportunity cost of time spent in intervention-related activities, including intervention and travel time, estimates were made using estimated time from the frequency and duration of contacts as reported by DPP staff. Travel time was estimated at 30 minutes. These times were multiplied by the value of \$8/hour which was 50% of the average hourly wage in 2000. Participants reported time spent in physical activity, shopping, and food preparation on a

questionnaire. For physical activity, time was valued at \$8 if the participant “disliked,” \$4 if “neutral,” and \$0 if they “liked” leisure-time physical activity. Shopping and food preparation were valued at \$4/hour. Round-trip transportation costs to DPP appointments were estimated at \$7/visit.

Questionnaires were used to capture the out-of-pocket costs of activity-related products and services, as well as food preparation equipment. If a given service or product was used by >5% of participants, it was included in the analyses. For specific purchases, it was assumed they were purchased once during the three year study period except for activity shoes (2 pair/year for lifestyle, 1 pair/year for the metformin and placebo group); health club memberships, exercise classes, weight loss programs (1.5 years’ attendance); personal trainer (five visits); and cooking classes (three classes). Durable equipment was defined as items that would last >3 years and cost more than \$100. These items were assumed to have 50% of their original purchase price after three years. The unit costs for the various products and services are provided in an appendix to the DPP paper [59].

A questionnaire also asked participants about any changes in food costs they experienced since they started in the DPP. Response options for food costs at home, fast food restaurants, and non-fast food restaurants included: “increased a lot,” “increased some,” “stayed the same,” “decreased some,” or, “decreased a lot.” “A lot” was assumed to be 10%, “some” was assumed to be 5%, and “stayed the same” was assumed to be 0% change. These percentages were then applied to the US per capita food expenditures from 2000 to estimate participant food costs.

### 5.3.2 DPP Cost Results

The DPP report compared direct nonmedical expenses for the three study arms during three years following the baseline visit. Only the per capita totals and differences in per capita values relative to the placebo are reported. Table 5.1 summarizes the expense estimates for the nonmedical expenses in the three DPP arms: placebo, metformin, and lifestyle, as presented in the original paper.

**Table 5.1 Summary of Direct Nonmedical Costs in the DPP, years 1-3**

	Placebo Costs (\$)	Metformin Costs (\$)	Lifestyle Costs (\$)	Metformin vs. placebo (\$)	Lifestyle vs. placebo (\$)
Participant time	5404	5530	6040	-52	637
Services	532	514	642	-18	110
Fitness equipment	165	148	223	-17	58
Food equipment	71	70	79	-1	9
Shoes	220	220	439	0	219
Food costs	9223	9226	9152	3	-71
Transportation Costs	79	154	562	76	484
Total	15692	15683	17137	-9	1445

DPP Group [59]

As would be expected given their participation in the intervention, those in the lifestyle group had greater time costs than the placebo group, a pattern that was present in all cost categories except food costs. There was a net decrease of \$71 in food costs in the lifestyle group,

compared to the placebo group. This is due to the lifestyle group spending \$79 less than the placebo on food eaten away from home and \$7 more on food at home (totals do not add up due to rounding) [59].

#### **5.4 PARTICIPANT COSTS IN INTERVENTION PROGRAMS BASED ON THE DPP**

While numerous diabetes prevention interventions based on the Diabetes Prevention Program (DPP) have reported clinical results in the years following publication of the original DPP findings, there has been only one report of direct, nonmedical expenses from such programs. Lawlor et al [60] reported these results from the Healthy Living Partnerships to Prevent Diabetes (HELP PD) trial, a 2-year intervention delivered by community health workers. The cost analyses are presented in a similar format to those of the DPP results [59], which the authors assert represent “good practice” and facilitate comparison with the DPP findings. In the HELP PD trial, cost information was collected by questionnaire at 6, 12, 18, and 24 months, with results reported from years 1-2. Not surprisingly, the intervention group had higher expenses due to the value of time spent in self-monitoring, physical activity, and travel costs related to the intervention, compared to the usual care group. Both groups had similar expenses for activity services and food-related items. In total, direct nonmedical expenses were \$955 higher in the intervention group, compared with usual care [60].

## **5.5 FOOD RECEIPTS COLLECTION**

An increase in the cost of household food is a direct, nonmedical expense that participants in a healthy lifestyle intervention for type 2 diabetes prevention may face. In order to evaluate this expense component, various strategies have been devised to ascertain food expenses.

In addition to self-reporting of household food expenses on a questionnaire, participant submission of food purchase receipts has been investigated as a way of assessing food expenses, as well as a way to validate self-reports. In a review, French et al [166] concluded that the annotated food purchase receipt method, used over two to four weeks, is the best option for providing feedback over time about changes in household food purchase patterns. Ransley et al [167] showed in a UK study that the fat and energy food items on supermarket till receipts had a strong linear association with actual energy (slope = 0.90, 95% CI 0.80 – 1.00) and fat (slope = 0.76, 95% CI 0.64 – 0.87) consumed, as measured by food diaries. French et al [168] reported a completion rate of 85% (90 of 106) among households completing a baseline visit submitted receipts during a 28-day collection project. In another study, DeWalt et al [169] found that the collection of grocery store receipts was relatively non-intrusive and easily carried out. As well, they reported that this method reduced participant burden relative to other methods and helped solve problems of participant non-response.

## **5.6 EXPENSE OF HEALTHY FOOD**

The perception that healthy food is more expensive than unhealthy food has been a continuing challenge to efforts that promote healthy food as a means of reducing disease risk and



maintaining an appropriate body weight. On this issue, there is apparently conflicting evidence. On one hand, diets containing a high proportion of calorie-dense foods appear to cost less per unit of energy than nutrient rich foods like fruits and vegetables. This has led some to conclude that, based on economic factors alone, consumer decisions would favor calorie-dense foods of low nutrient quality which contribute to obesity, and that obesity is thus largely an economic problem [170-172]. This view is supported by the observation that a low socioeconomic status is associated with higher rates of obesity among children, with the odds ratio for obesity increasing in the presence of low income: 2.91 (1.66-5.08) and medium income: 2.04 (1.21-3.44) [173].

However, other analyses have concluded that the costs per calorie of meeting national dietary recommendations from a fast food restaurant was 24% higher than with healthy food from a grocery store [174]. Additionally, Lipsky [175] has identified potential methodological weaknesses in analyses comparing energy density with energy cost, concluding that the relation between energy density and food price is confounded by the food category and thus cost per calorie may not be an appropriate measure of food price.

Another way of framing the issues is as a disagreement between observational studies, which often conclude that a healthy diet costs more, and intervention studies which indicate that dietary quality can improve with minimal if any increase in food expense. In an intervention study among breast cancer survivors, an increase in fruit and vegetable consumption from 6.3 to 8.9 servings per day was associated with a minimal but significant increase of \$1.22/week ( $p=0.027$ ) in grocery costs [176]. The Finnish Diabetes Prevention Study reported no significant increase in food costs for the intervention group, compared to the controls, even as diet quality improved [177]. Similarly, a pediatric family-based obesity intervention showed a significant decrease in dietary cost from baseline to one year (\$6.77 $\pm$ 2.41 to \$5.04 $\pm$ 1.80), by

emphasizing decreased consumption of energy dense foods and increased consumption of nutrient dense foods [178], although the cost-level of the supermarket (budget, midrange, or high street) was identified as a factor in cost increase or decrease in a UK study of obese children [179].

Ultimately, the conclusion depends to a great extent on how cost is measured. The US Department of Agriculture (USDA) Economic Research Service considered this issue in a report entitled *Are Healthy Foods Really More Expensive?* [58]. They concluded that foods lower in caloric density appear to have a higher price when price is measured per calorie. Thus, fruits and vegetables are a relatively expensive way to purchase food energy. Also, less healthy foods, especially those with high levels of saturated fat and sugar, tend to have a lower cost per calorie. However, based on edible weight or average portion size, grains, vegetables, fruit, and dairy foods are less expensive than most protein foods and foods containing high amounts of saturated fat, added sugars, and/or sodium.

It thus appears that while unhealthy food may be cheaper per calorie, cost need not be an obstacle to dietary improvement. Indeed there are examples showing that diets high in nutrition need not be expensive, including the Thrifty Food Plan from the USDA [180]. These conclusions are important for the field of diabetes prevention because behavioral lifestyle interventions encourage healthy dietary changes that may be perceived as financial obstacles to some participants. In the next section, the issue of expenses directly faced by participants will be further considered in an intervention setting, presenting results from a clinical trial delivered in the community.

## **6.0 PARTICIPANT EXPENSES IN A TRANSLATIONAL DIABETES PREVENTION INTERVENTION**

As around 15% of Americans, over 47 million, received federal Supplemental Nutrition Assistance Program (SNAP) benefits in April 2013 [181], the issue of food expenses is an important factor in the lives of many people. Socioeconomic factors have been shown to be associated with rates of type 2 diabetes [182], so there is good reason to recognize that many individuals at elevated risk of diabetes may view the prospect of changes to their dietary and activity patterns as part of a diabetes prevention program with caution and uncertainty, fearing increased expenses. There have been some reports addressing this topic, however questions remain as to the expenses faced by participants in diabetes prevention efforts.

In 2003, the direct per capita nonmedical expenses of participants in the Diabetes Prevention Program (DPP) clinical trial were reported [59], along with recent results from the HELP-PD study [60]. However, there are aspects related to participant expenses in translational diabetes prevention interventions that have yet to be thoroughly examined. These include statistical evaluation of change between and within intervention and control groups, and evaluation of intervention subgroups.

## **Overview of Chapter 6 Organization**

Chapter 6 of this dissertation examines direct nonmedical expenses that are paid out-of-pocket by participants in a translational type 2 diabetes prevention program. These are expenses related to food, participating in activity, and time in activities prescribed or recommended to participants in the intervention program.

For this dissertation, data was available from two of three settings of a translational research investigation focusing on issues and challenges related to delivery of diabetes prevention programs in diverse settings. In Section 6.1, the general background and methods are described. Section 6.2 presents baseline demographic results for both sites, and Section 6.3 presents six-month clinical findings. Section 6.4 includes the specific aims for and abstract of the third dissertation paper (Appendix C) which is randomized controlled trial (RCT) analyses. This section presents changes in expenses that occurred among participants from baseline to six months, as well as differences between the intervention and control groups. In section 6.5, 12-month pre-post results are presented, showing longer term changes from baseline to 12 months in one intervention subgroup. Section 6.6 presents expenses analyses of those participants who reported expenses at a given clinical visit, excluding those who report a value of \$0. Analyses of food receipts and food expenses reported in the expenses survey are in Section 6.7, followed by subgroup analyses by several demographic variables in Section 6.8 and cross-sectional workplace results in Section 6.9. Section 6.10 concludes with a comparison of self-reported six-month food expenses in both sites.

## **6.1 GENERAL BACKGROUND AND METHODS**

### **6.1.1 Setting**

In order to further address the issue of expenses faced by participants in a diabetes prevention intervention, an opportunity was available to collect and analyze data as part of an ongoing randomized controlled trial (RCT). Data were collected from two settings (community centers and a worksite) in Allegheny County, PA for this Group Lifestyle Balance (GLB) translational research study. Community data came from GLB participants at three community centers, consisting of two senior citizens centers that provide lunch and activities at little or no cost, as well as a religiously-affiliated community center that offers a wide variety of programming and services as well as a fitness center open to the general community. Workplace data is from the employees at a large international corporation in Allegheny County, PA. Funding for this translational investigation was provided by the National Institutes of Health (NIH) through the National Institute of Diabetes and Digestive and Kidney Disorders (NIDDK) to Principal Investigator Andrea Kriska, PhD, Professor of Epidemiology at the Graduate School of Public Health at the University of Pittsburgh.

### **6.1.2 Recruitment and Clinical Eligibility**

In the three community settings, recruitment posters were displayed both in the centers and in nearby public venues. Direct mail was used to target residents in zip codes surrounding the community centers. Names and addresses for the mailings were obtained from publicly available voter records at the Allegheny County elections office. At the workplace, corporate employee

communication channels were used to inform employees of the intervention as well as Lunch and Learn events where researchers from the University of Pittsburgh presented an overview of the planned investigation as well as answered questions.

In order to help identify individuals who were more likely to meet the clinical eligibility criteria for this investigation, a two-step screening approach was used at both sites. The first step consisted of an in-person or telephone pre-eligibility screening that quickly and easily identified a group of individuals who were more likely to meet clinical eligibility criteria. This step reduced the time and expense of the clinical assessments by reducing the number of ineligible individuals who attended the clinical assessment visit. Interested individuals meeting the screening eligibility criteria below were invited to attend an on-site clinical eligibility assessment visit:

- Aged 18 years or older
- No previous diagnosis of diabetes
- No plans to leave the area during the next 18 months
- (Women only) Not currently pregnant or breastfeeding. Not given birth in the past 6 weeks. No plans to become pregnant within the next 18 months
- BMI  $\geq$  24 (if Asian, BMI  $\geq$  22)

At the clinical assessment visit, one or more of the following three clinical conditions were necessary in order to be invited to enroll in the study:

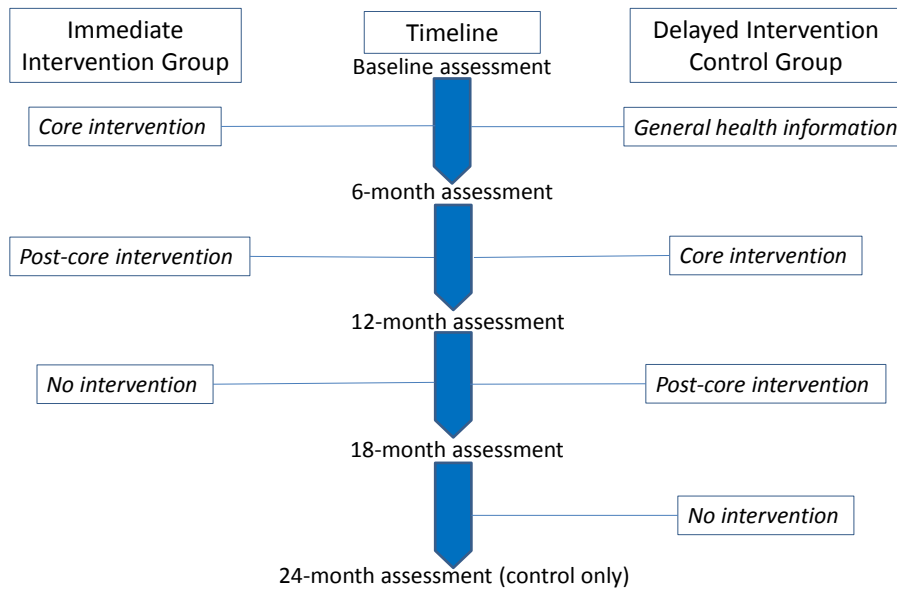
1. Prediabetes (fasting plasma glucose 100-125 mg/dl or HbA1C 5.7-6.4%)
2. The metabolic syndrome, as defined by the NCEP ATP III criteria [100]. The presence of three or more of the following conditions:
  - 1. elevated triglycerides ( $\geq$ 150 mg/dl)

- 2. low HDL cholesterol (<40 mg/dl for men, <50 mg/dl for women)
  - 3. increased waist circumference (>102cm for men, >88cm for women)
  - 4. blood pressure  $\geq$ 130/85 mm Hg (or on treatment for hypertension)
  - 5. elevated fasting plasma glucose ( $\geq$ 100 mg/Dl).
3. The presence of previously-diagnosed hyperlipidemia plus one other metabolic syndrome component

Additionally, a signed physician referral was required of those electing to enroll in the study.

### **6.1.3 Study Design, Data Availability, and Variables**

This GLB intervention used a delayed control design (Figure 6.1). This design was selected because it balances research expectations and ethics by providing intervention and control arms during the first phase of the randomized controlled trial (RCT), while meeting the ethical imperative to provide eligible participants who are at elevated risk of type 2 diabetes and/or have the metabolic syndrome, the opportunity to partake of a lifestyle intervention from which they should derive benefit, after a delay of six months. At baseline, two-thirds of the participants immediately began the intervention, while one-third were delayed for six-months before entering the identical intervention. This design allows direct comparisons to be made between the intervention and control groups at the six month clinical visit, enabling a prospective assessment of the effect of the intervention.



**Figure 6.1 Delayed Control Study Design**

#### **6.1.4 Expenses Ascertainment**

Participants expenses related to the intervention were ascertained in two ways: using an expenses survey (Appendix D) that was completed during clinical visits at baseline, and six- and 12-months, and by food purchase receipts submitted by the participants. The survey was compiled from a variety of sources and included items from the National Health and Nutrition Examination Survey (NHANES) Consumer Behavior Questionnaire [62], as well as questions about intervention-related travel time and expenses, food preparation patterns and time, purchases for physical activity and services, time and expenses of injuries sustained during physical activity, time and expenses of post-baseline diabetes diagnoses, hospitalizations and visits to the emergency room, physician office visits, and medication changes. Due to a delay in



preparation, the expenses survey was not available for the baseline assessment visit at the workplace. Full baseline data was obtained from the three community sites.

#### **6.1.5 Laboratory and Anthropometric Measures**

Clinical assessment visits were conducted at baseline and six and 12 months after the baseline visit. Participants met with the clinical team from the DPSC at their workplace or community enrollment site for the assessment visits. Clinical variables obtained via blood draw included total cholesterol, HDL cholesterol, LDL cholesterol, triglycerides, insulin, fasting plasma glucose, and HbA1C. Other measures included height, weight, blood pressure, and waist circumference. A brief medical history was taken that included family and personal history of chronic disease, medication use, and cardiovascular events. Surveys on self-monitoring habits, participant willingness to engage in various intervention-related activities, the Modifiable Activity Questionnaire (MAQ), as well as evaluation of the program and suggestions for improvement, were also given.

As mentioned previously, this community translational investigation is collecting data from participants in multiple sites. At the Workplace site, data collection is complete, while it continues at the three Community sites. This dissertation includes available data from both intervention settings, detailed in Table 6.1.

**Table 6.1 Data Availability by Intervention Site**

Workplace	Community
Baseline Assessment, 88 participants No expenses surveys or receipts collected	Baseline Assessment, 134 participants Immediate (baseline), 88 Delayed (1 <sup>st</sup> baseline), 46 132 costs surveys 87 receipts
6-Month Assessment Immediate (6 months), 52 Delayed (baseline), 28 80 costs surveys 38 receipts	6-Month Assessment Immediate (6 months), 84 Delayed (2 <sup>nd</sup> baseline), 42 122 costs surveys 68 receipts
12-Month Assessment Immediate (12 months), 46 Delayed (6 months), 22 68 costs surveys 33 receipts	12-Month Assessment Immediate (12 months), 77 Delayed (6 months), 37 114 costs surveys 43 receipts
18-Month Assessment Immediate (18 months), 47 Delayed (12 months), 21 21 costs surveys 10 receipts	18-Month Assessment Immediate (18 months), Delayed (12 months), costs surveys receipts

**Shading indicates available data**

Variables used in these analyses are derived from questions on the expenses survey (Appendix D). There are three categories of variables. Those related to participant time in various intervention-related activities are given in Table 6.2. Participants were encouraged to self-monitor their food and beverage intake, as well as record the time they spent in physical activity. Time spent related to meal preparation and clean up were also recorded. Each of these behaviors takes time and for the purpose of this investigation may be considered an expense to the participant.

**Table 6.2 GLB Participation Time Variables**

Variable Name	Variable Definition	Variable Source (Appendix D)
Time Self-Monitoring Activity	Average weekly time spent keeping track of physical activity in a log or journal	Q11, 13
Time Self-Monitoring Eating and Beverage Intake	Average weekly time spent keeping track of food and beverage intake in a log or journal	Q12, 14
Weekly Time Spent in Physical Activity	Average weekly time spent in physical activity over the last 6 months	Q15
Physical Activity Alternative	What participant would have been doing if not in physical activity	Q16
Times Preparing Main Meal at Home	Average number of times in a typical week over the last 6 months that participant or family member prepared food at home for the main meal	Q17a
Time Preparing, Cooking, and Cleaning Up	Average weekly time over last six month that is spent in preparing, cooking and cleaning up following the main daily meal	Q17b

Variables related to the expenses of physical activity encountered by participants are shown in Table 6.3. While being physically active need not necessarily incur expenses, the fact is that many individuals will purchase items to help facilitate physical activity, including shoes, clothing or other equipment. As well, particularly during seasons of the year when it is either too hot or too cold or icy outside, many people will find a gym or fitness center the best location in which to maintain their physical activity program.

**Table 6.3 GLB Physical Activity Expense Variables**

Variable Name	Variable Definition	Variable Source (from Expenses Survey, Appendix D)
Shoe Purchases	Participant purchases of exercise or activity shoes during the last 6 months (Y/N).	Q18
Number of Pairs Purchased	If exercise shoes were purchased, how many pair	Q18a
Shoes Expense	Total cost of exercise shoes	Q18b
Activity Items Purchased	Participant purchases of additional items to help with physical activity (Y/N)	Q19
Activity Items Expense	Total cost of items purchased by participant for activity over the last 6 months plus cost of shoes	Q18b, Q19
Activity Services Purchased	Participant purchase of services related to physical activity (Y/N)	Q20
Cost of Activity Services	Total cost of services purchased by participant for activity services over the last 6 months	Q20
Total Activity Expense	Total cost of items and services purchased by participant related to physical activity over last 6 months	Q18b, Q19, Q20

Probably the expenses of greatest interest to intervention participants are presented in Table 6.4, the variables related to the expenses of food from various types of stores. For most families, particularly those at a lower income level, food expenses will be one of the largest monthly budget items and any change in food expenses will have a significant effect on the overall household budget.

**Table 6.4 GLB Food Expenses Variables**

Variable Name	Variable Definition	Variable Source (from Expenses Survey, Appendix D)
Monthly Grocery Food Expense	Participant expense for average grocery store food over last 6 months. Monthly dollar value, or 4 X weekly value. Subtracting grocery non-food 4Xweekly or monthly total, if any.	Q21
Monthly Non-Grocery Store Food Expense	Participant expense for average non-grocery store food over last 6 months. Monthly dollar value, or 4 X weekly value.	Q23
Monthly Take Out Food Expense	Prepared food purchased outside home, or delivered to home. 4Xweekly or monthly average dollar value over last 6 months.	Q24
Monthly Eating Out Food Expense	Food expenses away from home, regardless of where eaten. 4Xweekly or monthly average dollar value over last 6 months.	Q25
Monthly Store Food Expense	Total food expenses at grocery and non-grocery stores. Sum of Monthly Grocery and Monthly Non-Grocery Store Food.	Q21, Q23
Total Monthly Food Expense		Q21, Q23, Q24, Q25

The NHANES consumer survey includes food purchase from four types of stores: grocery, non-grocery or other store that sells food, take-out food, and food eaten away from home. In some settings, for example when looking at inner city food deserts, it may make sense to differentiate between food purchased grocery and non-grocery stores. This distinction would

capture food purchased at small convenience or drug stores that may sell food. However, in a suburban setting it does not make sense, particularly due to recent changes in grocery retailing where WalMart and Costco are now some of the largest sellers of groceries. Recognizing this, a new category, “store food” was created, consisting of grocery and non-grocery store food.

#### **6.1.6 Data Analyses**

Descriptive statistics (mean, median, standard deviation, and inter quartile range (IQR)) were calculated for baseline, six- and 12-month expense and time variables. These variables were tested for change at 6- and 12-months from baseline using paired t-tests when the data was normally distributed and the Wilcoxon Signed Rank-Sum test when the data was not normally distributed. In order to test between groups, the independent sample t-test was used for normally distributed data and the Wilcoxon-Mann-Whitney test for data that is not normally distributed. The Spearman Rank-Order Correlation test was used to test correlations between variables.

Given the large number of “0” values that exist for some of the activity expense variables, the data were also analyzed when limited to “non-zero” values. Another way of expressing this would be to say “for those participants who have expenses or time in a given category, what are the values, and what change occurs over time?”

## **6.2 BASELINE CLINICAL RESULTS**

### **6.2.1 Intervention in the Community Setting, Baseline Results**

There were no significant differences between the immediate and delayed control groups at baseline in the community setting (Table 6.5). The average age of all participants was in the low 60s. Most of the participants (92%) were Caucasian. The participants were highly educated, with almost 56% having a college or graduate degree. Over 40% were retired, reflecting the use of seniors' centers as recruitment venues.

**Table 6.5 Baseline Characteristics of Community Participants**

	<b>Intervention Mean (sd) Median (IQR) (n=88)</b>	<b>Control Mean (sd) Median (IQR) (n=46)</b>	<b>p-between groups</b>
<b>Gender % female (n)</b>	65.9% (58)	69.6% (32)	0.67
<b>Age average (sd)</b>	62.8 (12.1)	61.9 (11.9)	0.66
<b>Weight (lbs)</b>	212.4 (46.3) 202.3 (181.3-241.5)	201.5 (37.1) 195.1 (176.8-220.4)	0.17
<b>Total Cholesterol (mg/dl)</b>	194.4 (37.8) 188 (174.5-211.5)	192.7 (43.9) 188 (157-223)	0.82
<b>HDL Cholesterol (mg/dl)</b>	50.8 (14.4) 50.5 (41-58)	49.2 (12.4) 49.0 (41-56)	0.52
<b>LDL Cholesterol (mg/dl)</b>	115.2 (33.3) 117 (90-133)	113.6 (41.5) 108.8 (78.5-142)	0.82
<b>Triglycerides (mg/dl) (median, IQR)</b>	122.5 (100-163)	137 (99-183)	0.30
<b>Glucose (mg/dl)</b>	96.0 (10.3) 94.0 (89-101)	95.9 (13.1) 93.0 (87-102)	0.94
<b>HbA1C (%)</b>	5.80 (0.32) 5.7 (5.6-5.9)	5.76 (0.33) 5.7 (5.6-5.9)	0.53
<b>Insulin</b>	6.84 (6.0) 5.00 (2-10)	7.89 (6.7) 6.00 (3-10.5)	0.37
<b>Systolic Blood Pressure (mmHg)</b>	118.2 (11.7) 118 (109.5-125)	119.1 (12.2) 118.5 (112-129)	0.67
<b>Diastolic Blood Pressure (mmHg)</b>	72.3 (8.8) 118 (109.5-125)	119.1 (12.2) 118.5 (112-129)	0.67
<b>Waist (inches)</b>	42.6 (5.8) 41.6 (38.6-45)	41.6 (4.7) 42 (38-44)	0.30
<b>BMI (kg/m<sup>2</sup>)</b>	34.9 (6.7) 33.6 (29.9 -38.7)	33.4 (4.9) 32.8 (30.3-37.0 )	0.16



## 6.2.2 Intervention at the Workplace Setting, Baseline Results

In the workplace setting the delayed control group was significantly younger than the immediate intervention group (53.4 vs 49.9 p=0.03) (Table 6.6). All other baseline variables were not significantly different between the two groups.

**Table 6.6 Baseline Characteristics of Workplace Participants**

	<b>Intervention Mean (sd) Median (IQR) (n=60)</b>	<b>Control Mean (sd) Median (IQR) (n=29)</b>	<b>p-between groups</b>
<b>Gender % female ( n)</b>	56.7% (34)	51.7% (15)	0.66
<b>Age average (IQR)</b>	53.4 (49.3-59.3)	49.9 (44.9-53.7)	0.03
<b>Weight (lbs)</b>	204.6 (40.1) 197.7 (177-229)	218.5 (36.6) 210.8 (194-241)	0.11
<b>Total Cholesterol (mg/dl)</b>	195.0 (37.9) 198.5 (165.5-218)	195.5 (37.7) 190.5 (166.6-214.5)	0.95
<b>HDL Cholesterol (mg/dl)</b>	53.2 (13.8) 50.5 (43.5-61.5)	47.8 (15.1) 46.5 (39-54)	0.10
<b>LDL Cholesterol (mg/dl)</b>	113.2 (33.3) 110.5 (85.5-137.5)	116.9 (26.7) 113 (99-131)	0.61
<b>Triglycerides (mg/dl) (median, IQR)</b>	134 (101-161.5)	139 (98.5-191.5)	0.60
<b>Glucose (mg/dl)</b>	92.1 (9.8) 91 (86-98)	91.8 (12.1) 88.5 (82-98.5)	0.90
<b>HbA1C (%)</b>	5.69 (0.31) 5.7 (5.5-5.9)	5.60 (0.23) 5.6 (5.5-5.7)	0.19
<b>Insulin</b>	5.66 (6.44) 3 (1-8)	9.11 (10.41) 7.5 (2.5-10)	0.12
<b>Systolic Blood Pressure (mmHg)</b>	121.1 (12.3) 120 (114.5-126.5)	120.0 (11.6) 118 (114-125)	0.70
<b>Diastolic Blood Pressure (mmHg)</b>	80.2 (8.4) 80 (76.5-85)	82.3 (8.1) 82 (78-87)	0.26
<b>Waist (inches)</b>	40.7 (5.2) 40.75 (37.7-43.1)	41.7 (4.5) 41 (39.25-44.25)	0.39
<b>BMI (kg/m<sup>2</sup>)</b>	32.8 (6.0) 31.2 (28.7-36.1)	33.6 (5.4) 32.7 (29.7-35.6)	0.55

## **6.3 SETTING THE STAGE: SIX-MONTH CLINICAL RESULTS AND INTRODUCTION TO PAPER 3**

### **6.3.1 Introduction to Six-Month Clinical Results**

In order to draw any valid conclusions as to whether or not the participants in this intervention experienced changes in food, activity, or time expenses, it must first be established that there was a significant reduction in risk factors for the metabolic syndrome and type 2 diabetes. In the absence of a statistically significant reduction in risk factors for type 2 diabetes or the metabolic syndrome, any finding of “no change” for expenses would be moot and contribute nothing to the translational literature related to diabetes prevention.

### **6.3.2 Six-Month Clinical Results**

In the immediate intervention group, there were significant decreases in weight, glucose, HbA1c, systolic blood pressure, waist circumference, and BMI (Table 6.7) at the six-month clinical visit when compared with the baseline visit. Of these, weight, HbA1c, waist, and BMI were all significantly decreased when compared with the delayed control group. These significant decreases in established risk factors for type 2 diabetes and components of the metabolic syndrome make it clear that participants in the behavioral lifestyle intervention did make changes in their dietary and/or physical activity behavior. The establishment of these clinical improvements allows legitimate considerations of whether these improvements were attained in the absence of increased spending for food and for physical activity.

**Table 6.7 Six Month Clinical Results—Community Setting**

<b>Variable</b>	<b>Delayed Group baseline I Mean (sd) Median (IQR) n=46</b>	<b>Delayed Group baseline II Mean (sd) Median (IQR) n=46</b>	<b>Mean Change (sd), Median (IQR) n=46</b>	<b>p</b>	<b>Immediate Group baseline Mean (sd) Median (IQR) n=88</b>	<b>Immediate Group 6 MO Mean (sd) Median (IQR) n=88</b>	<b>Mean Change (sd) Median (IQR) n=88</b>	<b>p</b>	<b>p diff between groups</b>
<b>Weight (lbs)</b>	201.5 (37.1) 195.1 (176.8-220.4)	199.9 (38.3) 194.0 (176.8-219)	-1.6 (7.0) -0.9 (-6.4-2.2)	0.13	212.4 (46.3) 202.3 (181.3-241.5)	201.5 (45.6) 194.7 (167-233.2)	-10.9 (10.9) -10.5 (-18.3- -2.9)	<.0001	<.0001
<b>Total Cholesterol (mg/dl)</b>	193.4 (45.0) 185.5 (156-226)	192.9 (40.0) 194.5 (161-218)	-0.5 (22.7) 0.5 (-12.5-14)	0.81	196.7 (37.3) 188 (177-212)	194.4 (35.7) 190 (171-210)	-2.3 (21.9) 0 (-15-9)	0.22	0.84
<b>HDL Cholesterol (mg/dl)</b>	48.7 (12.7) 48.5 (41-55)	47.2 (10.8) 46.0 (39.5-55.5)	-1.5 (6.8) -2.0 (-4-1.5)	0.11	51.3 (14.6) 49.5 (41-58)	50.3 (14.7) 47.0 (41-57)	-1.0 (6.7) -1.0 (-4-2)	0.06	0.19
<b>LDL Cholesterol (mg/dl)</b>	114.5 (42.1) 110.0 (78-142)	114.4 (35.1) 118 (84-136)	-0.1 (20.5) 0 (-8-16)	0.88	115.9 (33.4) 117.5 (94.5-132.5)	115.7 (30.8) 113.5 (95-130)	-0.2 (18.6) 0 (-11-10.5)	0.85	0.68
<b>Triglycerides (mg/dl) (med IQR)</b>	142.5 (95-198)	147.5 (105-212.5)	6.5 (-16.5-21.5)	0.64	122.5 (100-172)	126.5 (100-169)	0 (-20-20)	0.61	0.38
<b>Glucose (mg/dl)</b>	95.9 (13.1) 93.0 (87-102)	94.4 (12.2) 93.0 (86-100)	-1.7 (6.1) 0 (-4.0-2.5)	0.20	96.0 (10.3) 94.0 (89-101)	92.9 (10.8) 90.5 (86-97)	-3.1 (7.5) -2.5 (-5.5-0)	<.0001	0.25
<b>HbA1c (%)</b>	5.76 (0.33) 5.70 (5.6-5.9)	5.74 (0.41) 5.70 (5.5-5.9)	-0.02 (0.16) 0 (-0.1-0)	0.38	5.80 (0.32) 5.70 (5.6-5.9)	5.66 (0.29) 5.60 (5.5-5.9)	-0.14 (0.17) -0.10 (-0.2-0)	<.0001	<b>0.0002</b>
<b>SBP (mm/Hg)</b>	118.6 (12.3) 117.5 (111.5-127.5)	118.4 (14.3) 117.0 (109.5-128)	-0.25 (9.9) -2.0 (-7.5-6.5)	0.46	118.4 (11.7) 118.0 (110-125)	115.3 (12.6) 113.0 (108-122)	-3.12 (10.7) -2.0 (-10-3)	<b>0.01</b>	0.14
<b>DBP (mm/Hg)</b>	72.8 (11.6) 74.0 (68-80)	71.7 (10.0) 72.0 (65-79)	-1.1 (9.60) -0.5 (-7.5-5)	0.41	72.7 (8.6) 71.0 (68-78)	71.9 (9.6) 71.0 (65-78)	-0.9 (8.7) 0 (-8-5)	0.55	0.87
<b>Waist (in)</b>	41.5 (4.7) 42 (38-44)	41.5 (4.5) 41.0 (39.3-43.5)	-0.01 (1.9) 0.06 (-1.5-1.4)	0.96	42.6 (5.8) 41.6 (38.6-45)	41.0 (5.9) 40.0 (37.5-43.8)	-1.6 (2.0) -1.8 (-2.6- -0.1)	<.0001	<.0001
<b>BMI (kg/m<sup>2</sup>)</b>	33.4 (4.9) 32.8 (30.3- 37.0)	33.2 (5.2) 32.4 (29.9-36.4)	-0.3 (1.2) -0.2 (-0.9-0.4)	0.16	34.9 (6.7) 33.6 (29.9-38.7)	33.1 (6.9) 32.2 (27.3-37.7)	-1.8 (1.7) -1.8 (-2.9- - 0.5)	<.0001	<.0001

### **6.3.3 Background and Introduction to Paper 3 (See Appendix C)**

The presentation of participant expenses for this dissertation begins in Section 6.4. Paper 3 reports on expenses from the randomized controlled trial phase of the intervention during the first six months when there was both an intervention and control group. In this setting, it is thus possible to report baseline to six month expenses results, as well as compare changes in expenses and time between the two groups.

## **6.4 PAPER 3 (APPENDIX C). ACTIVITY AND FOOD EXPENSES AMONG PARTICIPANTS IN A COMMUNITY TRANSLATIONAL DIABETES PREVENTION INTERVENTION: BASELINE TO SIX MONTHS**

### **6.4.1 Specific Aims of Paper 3**

Paper 3 reports on the following specific aims:

**1. To describe changes in direct nonmedical expenses of participants partaking in a community diabetes prevention program.**

Results from the six-month assessment visit will be compared with baseline to evaluate change in direct nonmedical expenses for participants. As well, change between groups will be assessed to help quantify the impact of the intervention on participant time and expenses. These expenses are broadly defined, and include out-of-pocket expenses related to physical activity and food, and the time spent in intervention-related activities. In addition, these changes will be

reported with consideration of potential confounding variables, including age, gender, and education (a marker for socioeconomic status).

**2. To determine whether participants with higher attainment of program goals also accrue higher expenses associated with that attainment.**

Participants in the GLB program are given behavioral and weight-loss goals, based on the DPP lifestyle intervention. These include: weight-loss of 7% or greater and increased participation in physical activity. It is not clear whether those who reach established behavioral milestone also have greater direct, nonmedical expenses than those who do not attain program goals.

**6.4.2 Paper 3 Abstract (See Appendix C for Paper)**

**Activity and Food Expenses Among Participants in a Community Translational Diabetes Prevention Intervention**

**Purpose:** To evaluate direct nonmedical out-of-pocket expenses related to activity, food, and time among participants in a community translational diabetes prevention intervention.

**Methods:** Participant expenses related to the intervention were collected as part of a randomized controlled trial of a Group Lifestyle Balance (GLB) intervention in the community among individuals who had pre-diabetes and/or the metabolic syndrome. This included completion of expenses surveys and collection of household food receipts for two-week periods at baseline and six months. The intervention consisted of 12 weekly sessions followed by two bimonthly and then monthly sessions where participants received training and suggestions about how to make

and maintain healthy lifestyle choices. 134 participants (88 in the immediate intervention group and 46 in the delayed control group) enrolled in the study, allowing comparisons within and between the intervention and control groups.

**Results:** Among those with complete clinical attendance and survey results (n=91), total food expenses were unchanged from baseline to six months in the intervention group, while total food expenses significantly increased in the control group at six months when compared to baseline (+\$79.94  $p=0.04$ ). There was also a significant difference in the amount of money spent eating out between the control and intervention groups over the first six months of the program.

Although not at the level of significance, reported take-out food expenses appeared to decline in both the control and intervention groups. At six months, changes in total expenses for physical activity from baseline were not significantly different between the control and intervention groups. Expenses for physical activity services decreased significantly from baseline in the intervention group and approached significance in the control group. There was an increase of borderline significance for activity items in the control group from baseline at six months.

Adjusting food expenses data for food price inflation weakened the significance of the finding regarding eating out expenses between the control and intervention groups. Other food expenses results were unchanged after inflation adjustment. Stratification of change in expenses by achievement of weight loss, education, age and gender in the intervention group did not result in significant differences between groups, other than a significantly greater decrease in expenses for physical activity in men (196 to \$103,  $p<0.05$ ) than in women. There were no significant correlations between physical activity expenses or change in physical activity expenses and the monthly frequency or change of frequency of activities reported on the modifiable activity questionnaire (MAQ).

**Conclusions:** These findings suggest that statistically significant and clinically meaningful reductions in type 2 diabetes risk factors can be achieved without increasing household food and activity expenses. This is consistent with previously reported clinical and community results. However, unlike earlier reports, this study included baseline measures and was thus able to evaluate change over time. These expenses data are household level, and thus do not allow conclusions about individual consumption or use. However, the findings support the assertion that participants in a diabetes prevention program can adjust their individual dietary and activity patterns within their economic situation as part of a program to reduce their diabetes risk factors, without increasing expenses. Such a message may help dispel the myth that it costs more to make healthy lifestyle changes, and increase the attractiveness of diabetes prevention programs to those at elevated risk.

**Paper 3 Findings in the Context of this Dissertation:** The findings presented in Paper 3 are analyses of the first six months of data from the community setting. This is the randomized controlled trial (RCT) portion of the project. These results suggest that at-risk individuals can improve their clinical risk factors for type 2 diabetes and/or metabolic syndrome components without a significant increase in expenses beyond the time spent on intervention-related activities.

However, there are additional data available from this ongoing clinical trial from the 12 month assessment of the immediate intervention group (Table 6.1). It is instructive to report analyses of these data, comparing baseline to 12 months (or pre-post), as the GLB program is complete by 12 months and thus the participants have received all of the intervention doses. As well, seasonal effects will be eliminated as the baseline and 12 month assessment visits took

place approximately one year after the baseline visit. These pre-post 12 month results are reported in Section 6.5.

## **6.5 PARTICIPANT EXPENSES IN IMMEDIATE INTERVENTION GROUP-- BASELINE TO 12 MONTHS IN THE COMMUNITY SETTING**

As the Group Lifestyle Balance (GLB) investigation that provided participant expenses data for this dissertation is ongoing (see Table 6.1), complete prospective analyses cannot yet be completed. This section presents analyses of complete data participants in the community setting who attended both the baseline and 12 month assessment visits. When looking at both the purchase locations (store, take-out, eating out, and total food spending) there were no significant changes in total estimated food expenses from baseline to 12 months (Table 6.8). In all cases, the differences in the dollar amounts from baseline to 12 months were less than \$10, strongly supporting the evolving thesis of little or any change in food expenses over the course of the intervention.



**Table 6.8 Food Expenses by Purchase Site in the Immediate Intervention Group**

<b>Estimates of average monthly food purchase amounts per month over last 6 months</b>	<b>Baseline Mean (sd) Median (IQR) n=51</b>	<b>12 Mo Mean (sd) Median (IQR) n=51</b>	<b>Change Mean (sd) Median (IQR)</b>	<b>p</b>
<b>Store food (grocery and non-grocery, (\$/household)</b>	463.73 (301.55) 410 (260-600)	471.53 (291.95) 400 (250-600)	7.80 (338.91) 15 (-140-95)	0.89
<b>Purchased take-out food % (n)</b>	70.5% (36)	56.9% (29)	-13.6% (-7)	0.23
<b>Take-out food per month (\$/household)</b>	43.43 (48.60) 25 (0-80)	38.63 (53.79) 20 (0-50)	-4.81 (54.05) 0 (-25-0)	0.41
<b>Purchased eat-out % (n)</b>	94.1% (48)	92.2% (47)	-1.9% (-1)	1.0
<b>Eating out food per month (\$/household)</b>	130.73 (123.71) 100 (25-200)	135.63 (122.78) 100 (40-200)	4.90 (79.97) 5 (-25-32)	0.53
<b>Total of estimated food spending per month (\$)</b>	637.88 (386.02) 580 (380-840)	645.78 (350.69) 530.00 (400-965)	7.90 (385.74) 20 (-165-125)	0.93

For the immediate intervention group in the community setting, expenses related to physical activity from baseline to 12 months, both items and services, as well as the total, are reported in Table 6.9. Looking at the individual subcategories as well as the total, there were no significant changes reported from baseline to the 12-month assessment visit. As mentioned previously, these pre-post 12 month data control for seasonal factors that may have impacted purchase patterns reported in Paper 3, Table 3, where there were significant and borderline significant changes in purchases related to physical activity.

**Table 6.9 Expenses Related to Physical Activity in the Immediate Intervention Group**

<b>Household Activity Expense Categories (\$/6 months)</b>	<b>Baseline Mean (sd) Median (IQR) n=74</b>	<b>12 Months Mean (sd) Median (IQR) n=74</b>	<b>Change Mean (sd) Median (IQR)</b>	<b>p</b>
<b>Items (ex. shoes, clothing, bike)</b>	60.95 (132.03) 19.5 (0-80)	64.65 (104.44) 17.5 (0-90)	3.70 (160.72) 0 (-50-55)	0.68
<b>Services (ex. classes, gym membership)</b>	147.59 (354.04) 0 (0-60)	125.92 (355.38) 0 (0-80)	-21.68 (169.46) 0 (0-0)	0.29
<b>Total</b>	208.54 (375.32) 77.50 (0-240)	190.57 (378.13) 83 (0-190)	-17.97 (218.51) 0 (-60-50)	0.78

Time spent in intervention-related activities and food preparation from baseline to 12 months in the immediate intervention group in the community (Table 6.10) not surprisingly shows a significant increase in the time spent in intervention-related self-monitoring of physical activity (3.18 to 16.88 minutes,  $p<.0001$ ) and food and beverages (8.92 to 24.31 minutes,  $p<.0001$ ). As well for both categories of self-monitoring at 12 months, the median values are greater than zero, unlike at baseline, indicating that more than half of the participants continue to self-monitor one year after baseline. This finding is important because it has been shown that adherence to self-monitoring is associated with maintaining weight loss and high physical activity levels [183,184].

**Table 6.10 Time in Intervention-Related Activities in the Immediate Intervention Group**

	<b>Baseline Mean (sd) Median (IQR)</b>	<b>12 Months Mean (sd) Median (IQR)</b>	<b>Change Mean (sd) Median (IQR)</b>	<b>p</b>
<b>PA self-monitoring (minutes/wk) n=58</b>	3.81 (12.71) 0 (0-0)	16.88 (19.76) 10 (0-30)	13.07 (22.13) 6 (0-30)	<b>&lt;0.0001</b>
<b>Food self-monitoring (minutes/wk) n=51</b>	8.92 (29.84) 0 0-0	24.31 (26.06) 20 0-45	15.39 (32.51) 5 (0-30)	<b>&lt;0.0001</b>
<b>Food Preparation and Clean Up (minutes/wk) n=63</b>	456.03 (235.25) 420 (300-600)	412.95 (288.61) 360 (150-540)	-43.08 (305.94) -50 (-210-120)	0.14

## **6.6 ANALYSIS OF THOSE PARTICIPANTS REPORTING EXPENSES FOR PHYSICAL ACTIVITY**

In the randomized controlled trial results for physical activity expenses (Table 3 of Paper 3) and 12 month pre-post physical activity expenses (Table 6.9), inter quartile ranges (IQR) for physical activity items and for physical activity services have a low value of zero. This value of zero results from at least 25% of participants not reporting any expenses in those categories. Additionally, median values of zero are also present in both tables which further results from at least 50% of participants not reporting any physical activity expenses in these categories. This suggests that a substantial proportion of all participants did not report any physical activity expenses at all at the assessment visits. Accordingly, mean and median values for the participants as a whole may not accurately convey actual participant purchasing behavior.

Table 6.11 includes only those participants reporting physical activity expenses at each clinical assessment visit. In this analysis, the participants are not the same at each assessment time, and there is no consideration given to whether they did or did not have previous physical activity purchase. The “n” in each case is the number of participants attending the given assessment visit. In both the control and intervention groups, no clear patterns emerge, other than a continuing decline in the mean values. There is, however, no evidence that expenses increase over time in either the delayed control or immediate intervention groups.

**Table 6.11 Total Activity Expenses For Community Participants Reporting Expenses Greater Than Zero**

<b>Household Activity Expense (\$/6 months)</b>	<b>Control Baseline I % (n) reporting Mean (sd) Median (IQR) n=46</b>	<b>Control Baseline II % (n) reporting Mean (sd) Median (IQR) n=42</b>	<b>Control 6 Months % (n) reporting Mean (sd) Median (IQR) n=37</b>	<b>Intervention Baseline % (n) reporting Mean (sd) Median (IQR) n=88</b>	<b>Intervention 6 Months % (n) reporting Mean (sd) Median (IQR) n=81</b>	<b>Intervention 12 Months % (n) reporting Mean (sd) Median (IQR) n=77</b>
<b>Total</b>	63.0% (29) 291.69 (322.23) 204 (92-425)	73.8% (31) 244.72 (226.44) 170 (80-355)	59.5% (22) 458.75 (813.33) 140 (100-379)	70.5% (62) 358.76 (587.11) 201 (75-410)	64.2% (52) 280.69 (454.50) 151.50 (70-235.50)	64.9% (50) 282.04 (432.08) 142.50 (76-310)

## **6.7 RECEIPTS ANALYSES**

### **6.7.1 Introduction and Background**

In addition to the self-reported food expenses captured by the expenses survey, household food receipts collected and submitted by intervention participants in the community setting over a two week period near the assessment visits provided an additional source of information about food purchases. Receipt collection formed an ancillary study to the investigation, and all participants were invited to take part. Upon receipt of the receipts, research staff made photocopies of the receipts for archival purposes. Each receipt was then categorized into one of four general purchase types: grocery store, other food store, take-out, and eating-out. Store receipts were also scrutinized to identify and subtract non-food items from the total amount. As with the expenses survey, food amounts from grocery and other food stores were combined into a single store food category.

### **6.7.2 Results**

A substantial number of participants did not submit receipts despite encouragement to do so by research team personnel at the assessment visit as well as reminder telephone calls. Reasons given included the following: variants of “it’s too much bother,” “I’m a nanny and my employer family provides my food,” and “my wife/husband does most of the shopping and she/he won’t do it.”

Complete baseline and six-month receipts collection and survey data were available from 37% (49/134) of participants in the community setting. These participants attended both the baseline and six-month clinical visits, submitted household food receipts at both visits, completely filled out the expenses surveys (no “I don’t know” or missing data). This subset of the population provided the most complete expenses data and thus allowed the evaluation of expenses results from the same group of participants using two different measures, the expenses survey and food receipts. At six months from baseline, there were no significant changes in food expenses in either the control or intervention group based on submitted receipts, both from the purchase location categories, and in total (Table 6.12). As well, there were no significant changes in expenses between the two study groups.

**Table 6.12 Food Purchase Receipts Among Receipts and Survey Completers**

	<b>Delayed Group baseline I Mean (sd) Median (IQR) n=20</b>	<b>Delayed Group baseline II Mean (sd) Median (IQR) n=20</b>	<b>Delayed Group Baseline I to II Change Mean (sd) Median (IQR) n=20</b>	<b>p</b>	<b>Immediate Group baseline Mean (sd) Median (IQR) n=29</b>	<b>Immediate Group 6 MO Mean (sd) Median (IQR) n=29</b>	<b>Baseline to 6 MO Change Mean (sd) Median (IQR) n=29</b>	<b>p</b>	<b>p diff between groups</b>
<b>Store food (grocery and other store) (\$/household)</b>	260.03 (200.83) 246.25 (99.56-326.23)	202.56 (152.67) 194.81 (63.58-301.20)	-57.46 (225.51) -46.82 (-146.03-71.26)	.33	511.81 (720.28) 245.32 (170.74-465.96)	390.15 (324.82) 246.64 (189.98-557.30)	-121.66 (509.57) -11.08 (-106.84-94.94)	.45	.78
<b>Take-out food per month (\$/household)</b>	23.08 (67.90) 0 (0-10.25)	11.91 (20.93) 0 (0-12.83)	-11.17 (73.54) 0 (-10.25-10.70)	.99	9.28 (17.38) 0 (0-12.16)	11.80 (30.57) 0 (0-0)	2.51 (29.24 ) 0 (0-0)	.95	.94
<b>Eating out food per month (\$/household)</b>	101.90 (106.45) 62.33 (10.61-176.27)	88.32 (87.49) 68.18 (34.25-106.82)	-13.58 (134.68) 5.94 (-84.95-42.63)	.76	123.37 (182.78) 34.18 (0-147)	70.99 (93.18) 25.00 (0-139.18)	-52.38 (168.06) 0 (-82.36-15.14)	.13	.36
<b>Total food spending per month (\$)</b>	385.01 (274.43) 361.12 (163.84-467.97)	302.79 (192.76) 286.21 (140.25-462.11)	-82.22 (296.83) -3.11 (-107.95-88.52)	.59	644.47 (741.73) 350.90 (252.82-639.12)	472.94 (301.67) 404.74 (246.64-573.08)	-171.53 (543.97) -66.04 (-167.74-89.42)	.28	.58



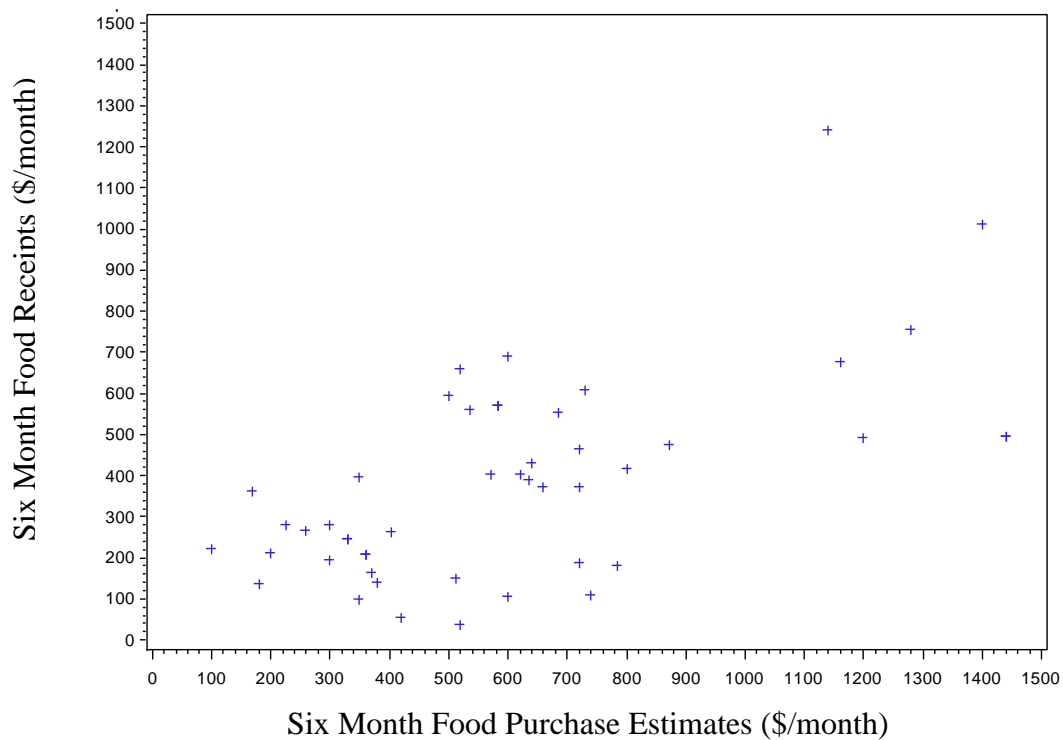
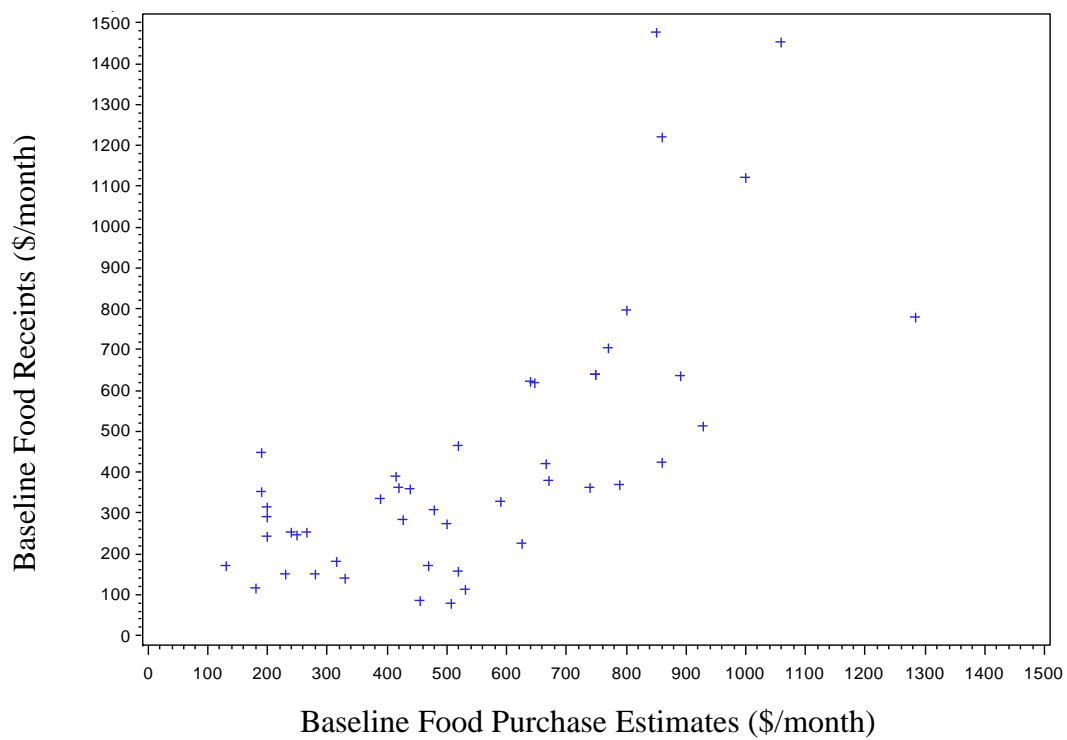
Food expenses reported on the expenses survey by the 49 receipts and expenses survey completers (same participants as in Table 6.12), also show no changes in food expenses, either from the various purchase locations, or in total.

**Table 6.13 Food Purchase Survey Estimates Among Receipts and Survey Completers**

	<b>Delayed Group baseline I Mean (sd) Median (IQR) n=20</b>	<b>Delayed Group baseline II Mean (sd) Median (IQR) n=20</b>	<b>Delayed Group Baseline I to II Change Mean (sd) Median (IQR) n=20</b>	<b>p</b>	<b>Immediate Group baseline Mean (sd) Median (IQR) n=29</b>	<b>Immediate Group 6 MO Mean (sd) Median (IQR) n=29</b>	<b>Baseline to 6 MO Change Mean (sd) Median (IQR) n=29</b>	<b>p</b>	<b>p diff between groups</b>
<b>Store food (grocery and other store) (\$/household)</b>	354.55 (185.96) 328.00 (220.00-440.00)	413.65 (271.63) 400.00 (240-500)	59.10 (226.18) 0 (-83-139)	.57	440.97 (265.46) 400 (230-640)	502.38 (353.05) 440 (300-600)	61.41 (214.27) 40 (-70-100)	.26	.62
<b>Take-out food per month (\$/household)</b>	25.15 (31.27) 5.00 (0-54)	19.75 (32.95) 0 (0-30)	-5.40 (35.62) 0 (-22.50-11)	.51	32.07 (35.94) 20 (0-60)	25.69 (40.37) 5 (0-24)	-6.38 (35.51) 0 (-20-0)	.13	.54
<b>Eating out food per month (\$/household)</b>	169.10 (113.42) 160 (80-225)	211.00 (157.64) 160 (110-300)	41.90 (135.00) 14 (-35-125)	.27	96.03 (104.88) 60 (25-140)	93.83 (102.10) 40 (0-160)	-2.20 (87.26) 0 (-30-30)	.95	.30
<b>Total food spending per month (\$)</b>	548.80 (228.42) 525 (424-705)	644.40 (360.81) 617.50 (375-735)	95.60 (314.41) -15 (-77.50-219)	.51	569.07 (322.71) 508 (265-790)	621.90 (379.70) 536 (350-720)	52.83 (235.28) 35 (-65-160)	.27	.78

Scatterplots of the receipts and survey food expense data (Figure 6.2) suggest possible linear relationships between the two measures, permitting the use of correlation coefficients to test the significance of the relationship between the food expense measures. The y-axis on the baseline plot (Figure 6.2) was set at \$1500, resulting in the truncation of two outlying data points. At baseline, Spearman's rank correlation coefficient for food receipts and reported food expenses was 0.73 ( $p < 0.0001$ ) and at six months the coefficient was 0.69 ( $p < 0.0001$ ).

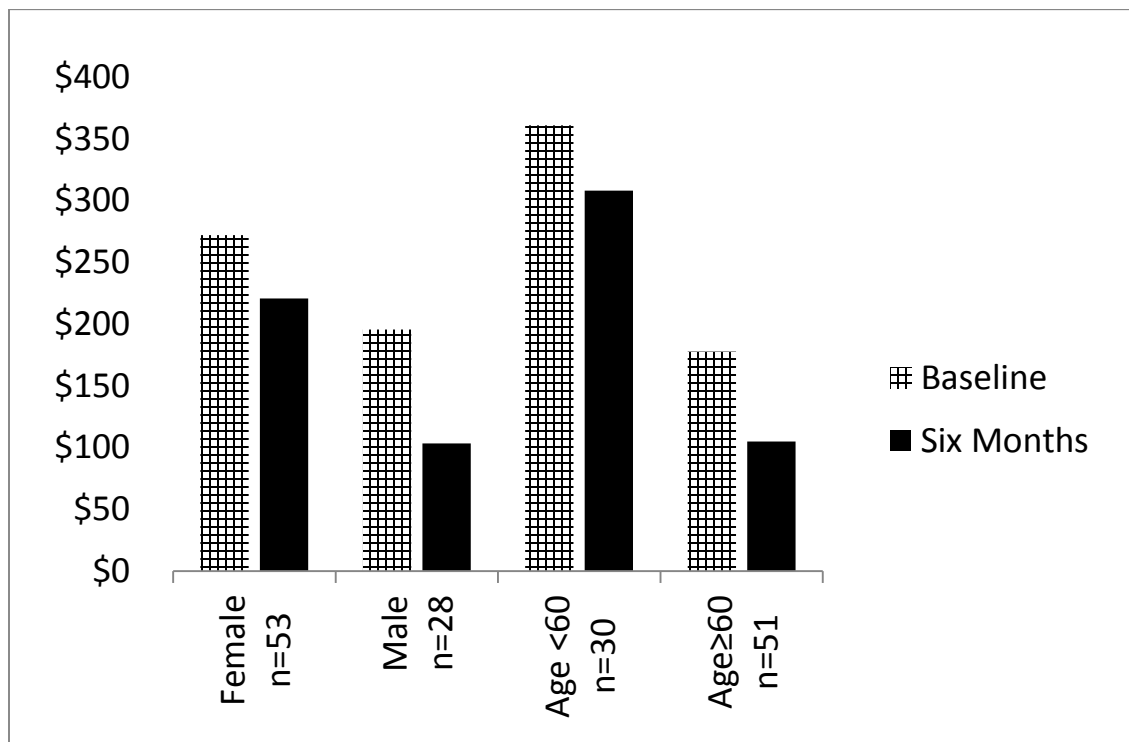
While correlations between the two measures of food expenses are positive and significant, the directions of change at six months are mostly in opposite directions, with average food purchase receipts decreasing in all categories except for take-out food in the immediate intervention group which increased \$2.51, while most categories appear to increase in the survey estimates, although not significantly. Explanations for this discrepancy may include a decreased thoroughness and completeness of receipt collection and submission by those who submitted receipts at six months. A participant was considered a "receipts completer" regardless of the number of receipts submitted. Some submissions only contained a single receipt, almost certainly underreporting household food expenses for that two-week period. Alternatively, granting that receipts collection was largely complete and accurate, it is possible that program participants became more aware of their food purchases by collecting receipts and through involvement in the intervention. As they became more aware of their food purchase habits and the amounts they were spending, they may have overestimated the actual amounts they spent in the various food purchase categories on the survey. It thus appears that while receipts collection and expense survey reports of food purchases are positively correlated, there may be some methodological or adherence issues that limit the accuracy of one or both as measures of change in food expenses over time.



**Figure 6.2 Scatterplot of Baseline and Six Month Food Purchase Receipts and Survey Estimates Among Completers (n=49)**

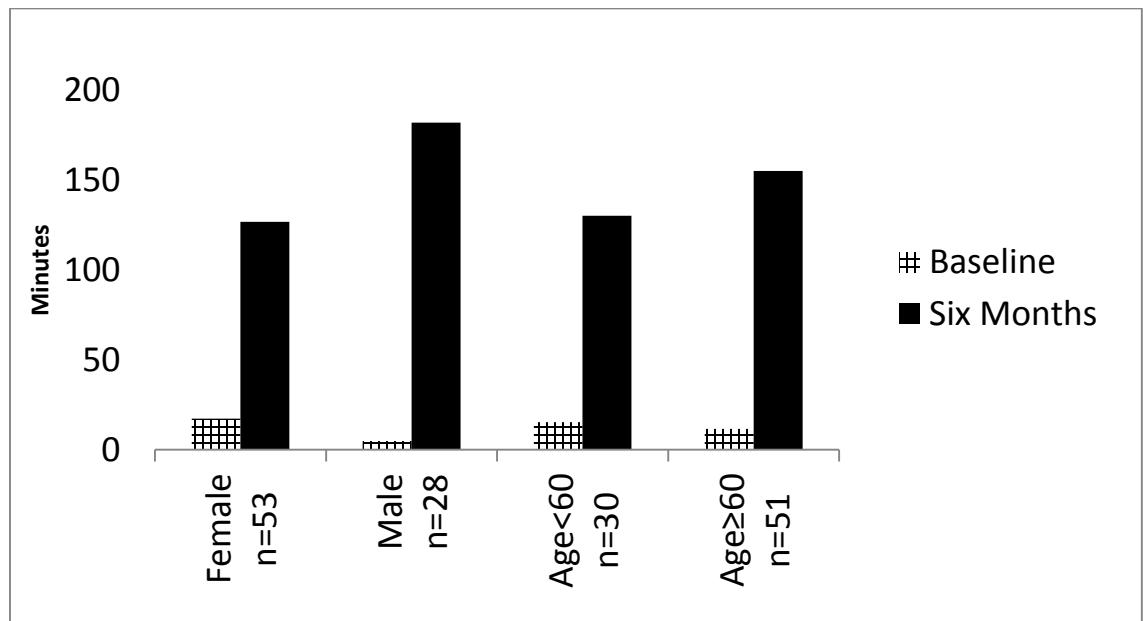
## 6.8 DEMOGRAPHIC SUBGROUP ANALYSIS

In order to evaluate whether participant experience in terms of expenses differed by subgroup, a series of stratified analyses follow, including tests of significance of the change between the stratified groups in the immediate intervention group from baseline to six months. Stratification of physical activity expenses (total of items and services) by gender and age showed that the decrease in expenses was significantly greater in males than in females (Figure 6.3).



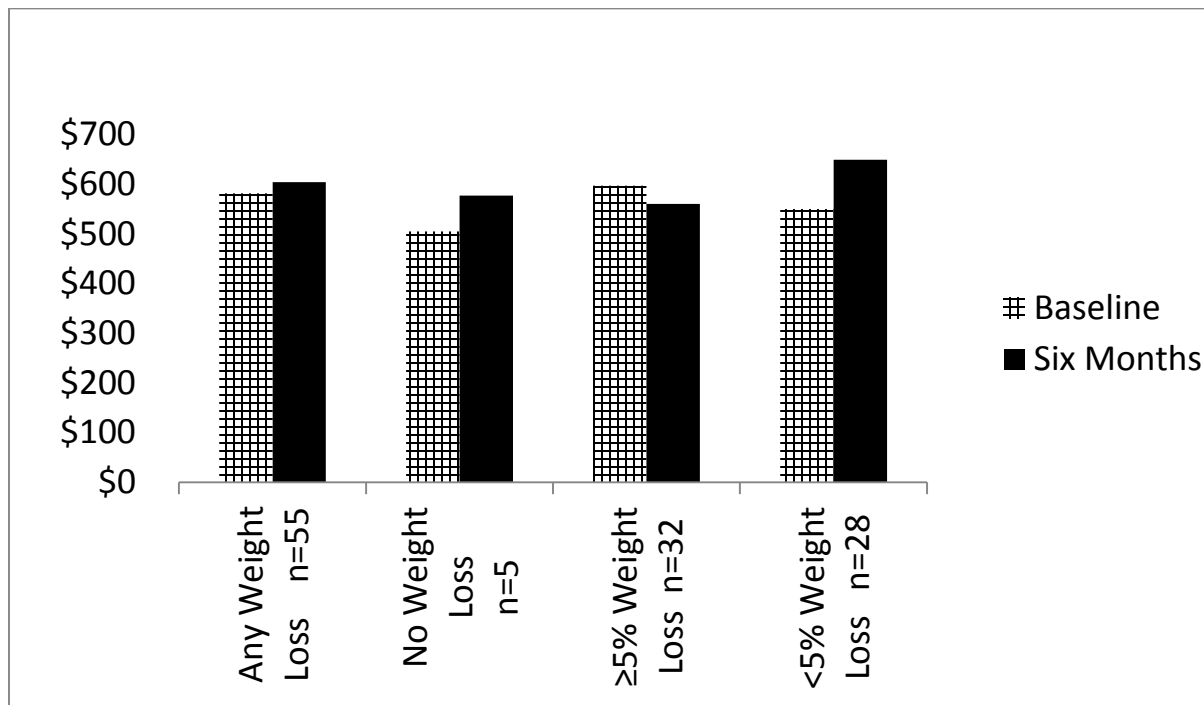
**Figure 6.3 Total Six Month Expenses for PA by Gender and Age in Immediate Intervention Group**

Although there were significant increases in time spent self-monitoring in all gender and age groups, there were no differences by gender or age in the degree of change in self-monitoring time (Figure 6.4).



**Figure 6.4 Weekly Self-Monitoring Time by Gender and Age in Intervention Group (minutes)**

Change in total food expenses was not significantly different when stratified by achievement of any and 5% weight loss from baseline (Figure 6.5).



**Figure 6.5 Total Estimated Monthly Food Expenses by Weight Loss in Intervention Group**

These results suggest that, in general, participants in various demographic groups had similar experiences in terms of the time they spent in intervention-related self-monitoring and for expenses for food and physical activity. As well, weight loss was not related to change in food purchases. It appears that the general behavior and experience of various participant groups may be quite similar.

## **6.9 CROSS-SECTIONAL WORKPLACE FOOD EXPENSE RESULTS**

Baseline food expenses data were not collected at the workplace due to a delay in preparation of the expenses survey form. It was thus not possible to evaluate change in food expenses over time for this population as was done in Paper 3 for community center participants. However, data were available to do cross-sectional comparisons of workplace food expenses reported by the control and immediate intervention groups at the six- and 12-month assessment visits.

The six-month assessment (Table 6.14), compares food expenses for the delayed control group which had yet to start the lifestyle program with the intervention group which had completed the core intervention sessions and was meeting monthly for the post-core material. For the 12-month assessment, food expenses of the delayed control group, having completed six months of intervention, are compared with the immediate intervention group which had completed the entire lifestyle intervention.

At both clinical visits, there were no significant differences between the immediate intervention and delayed control groups for total household food purchase expenses, as well as for the individual purchase location categories (Table 6.14). These results are consistent with an emerging trend in which there are no significant increases in expenses for participants in this behavioral lifestyle intervention, in either the community or workplace setting.



**Table 6.14 Six- and Twelve-Month Cross-Sectional Analysis of Monthly Food Expenses in Workplace Participants**

	<b>Six-Month Assessment</b>			<b>Twelve-Month Assessment</b>		
<b>Monthly Food Expenses by Site (\$/household)</b>	<b>Control Baseline Mean (sd) Median (IQR) n=21</b>	<b>Intervention Six Months Mean (sd) Median (IQR) n=29</b>	<b>p</b>	<b>Control 6 Months Mean (sd) Median (IQR) n=14</b>	<b>Intervention 12 Months Mean (sd) Median (IQR) n=26</b>	<b>p</b>
Store food (grocery and non-grocery,	538.33 (267.51) 520 (350-680)	554.48 (250.25) 455 (385-720)	.95	406.00 (195.33) 345 (300-500)	415.15 (190.06) 397.50 (304-520)	.66
Take-out food per month	67.38 (52.91) 80 (350-680)	74.14 (85.38) 50 (20-100)	.83	78.21 (74.10) 42.50 (30-100)	69.62 (83.15) 50 (20-80)	.54
Eating out food per month	191.19 (129.05) 200 (100-300)	207.93 (152.54) 160 (100-250)	.98	178.93 (126.00) 200 (100-240)	166.73 (143.59) 120 (75-200)	.56
Total of estimated food spending per month	796.90 (339.79) 770 (620-980)	836.55 (338.29) 760 (585-1020)	.85	663.14 (289.47) 665 (480-800)	651.50 (273.62) 582.50 (470-870)	.77

## **6.10 COMPARISON OF SELF-REPORTED FOOD EXPENSES IN COMMUNITY AND WORKPLACE SETTINGS**

The two intervention settings, community and the workplace, were chosen because they represented different demographics. While the primary expenses results in this dissertation have been changes within and between the experimental and control groups, as well as pre-post results in the community setting, Table 6.15 extends the analyses by showing a comparison of the food expenses of participants in the two intervention settings. The expenses reported for each setting are from the identical stage in the intervention for all participants: the six-month clinical visit for the immediate intervention group and the 12-month visit for the delayed control group. At these points, all participants had received six months of intervention consisting of the 12 core sessions and some of the post-core sessions.

**Table 6.15 Cross-Sectional Comparison of the Self-Reported Food Expenses of Workplace and Community Participants after Having Completed Six Months of Intervention**

<b>Monthly Food Expenses by Site (\$/household)</b>	<b>Community Mean (sd) Median (IQR) n=66</b>	<b>Workplace Mean (sd) Median (IQR) n=44</b>	<b>p</b>
Store food (grocery and non-grocery,	475.44 (314.00) 420 (250-600)	400.59 (239.65) 372.50 (176-500)	.19
Take-out food per month	34.76 (48.17) 11 (0-52)	78.55 (77.77) 74 (30-88)	<.0001
Eating out food per month	141.36 (139.56) 116 (40-200)	156.05 (115.98) 100 (88-200)	.42
Total of estimated food spending per month	651.56 (380.65) 560 (360-850)	635.18 (324.05) 585 (352-780)	.91

With the exception of significantly greater expenses for take-out food at the workplace (\$78 to \$35,  $p < .0001$ ) (Table 6.15), other food expenses, including total food expenses, were not different between the community and workplace settings. This result is somewhat surprising, given the generally higher socioeconomic level of the workplace participants. However, among the community participants there were a number of highly educated and apparently affluent individuals, who, along with a several very large families, likely contributed substantially to food expenses in the community, resulting in similar results as the workplace.

## **7.0 FINAL CONSIDERATIONS**

### **7.1 SUMMARY CONCLUSIONS**

Taken in totality, the findings of this dissertation illuminate an aspect of behavioral lifestyle interventions for preventing type 2 diabetes in the community setting that has not been extensively investigated, that of participant experience in such translation programs. This dissertation provides support for the assertion that there are direct benefits to participants beyond the reduction of clinical risk factors for type 2 diabetes and/or metabolic syndrome components. These include improvements in health-related quality of life (HRQoL), and that successful risk factor reduction can occur in the absence of significant increases in direct nonmedical expenses to the participant.

Paper 1 reported on HRQoL in a Group Lifestyle Balance (GLB) intervention delivered by trained diabetes educators at three outpatient diabetes education sites. Over the course of the intervention, several improvements in HRQoL emerged, measured by the CDC HRQoL–14 Healthy Days Measure survey. These included reductions in the number of days the participants felt they did not get enough rest or sleep and an increase in the number of days they felt healthy and full of energy. Additionally, it was shown that participants who attended half or more of the GLB sessions were more likely to have reported fewer than 14 unhealthy days in the past month. These improvements provide evidence that participants at risk for type 2 diabetes and/or had the

metabolic syndrome benefitted in measurable ways from the GLB program beyond the previously established changes in physiologic outcome measures. While improvements in HRQoL were previously shown in participants in the DPP clinical trial [52], the findings presented here strengthen and broaden the translational literature in the field of community diabetes prevention.

Paper 2 builds on the findings of Paper 1 by evaluating HRQoL in a different setting and using an alternate HRQoL assessment tool. The HRQoL data for that series of analyses came from a GLB intervention that pilot-tested delivery of the intervention via DVD as an alternative to the usual group setting. While not powered to distinguish between the two delivery modes, both were shown to successfully reduce the risk factors for type 2 diabetes. The Euro-Qol Visual Analog score, which represents the participants rating of their overall health on a scale of 1-100, improved significantly among both the group and DVD delivery participants. These findings provide additional evidence that among those at elevated risk of type 2 diabetes, a prescription of a healthier lifestyle helps in ways beyond reduction of clinical risk factors.

In addition to the findings related to HRQoL, this dissertation examined direct nonmedical expenses for individuals participating in a community lifestyle intervention translation effort. Examples of such expenses include food, activity items and services, as well as time related to the intervention. These expenses were reported in the DPP [59] and in translation from the HELP-PD intervention [60]. In both cases the intervention participants reported little difference in retrospectively-reported direct nonmedical expenses. This dissertation adds to the translational literature by strengthening the case that there is little change in direct nonmedical expenses among the intervention participants when compared to the control group. This finding was based upon both the lack of change in reported expenses from baseline

to 6 months (post intervention) in the intervention group compared to the control group, as well as any substantial pre-post change within either group. The story that continues to emerge is that healthy lifestyle changes and reductions in disease risk can be achieved by participants in a behavioral lifestyle intervention for diabetes prevention without significant additional expenses, beyond the time invested in attending the intervention and involvement in intervention-related activities.

These findings regarding expenses have important economic implications given the financial burden of type 2 diabetes. Currently, 1 of every 10 healthcare dollars in the US attributed to the cost of diabetes [7], mostly type 2 diabetes. By scaling up translational approaches based on the Diabetes Prevention Program, it should be possible to reduce financial burden of diabetes by preventing the disease or delaying its onset. While such interventions have previously been shown to be cost-effective [156], the findings presented here have shown that risk factors for type 2 diabetes can be reduced within the existing budgetary and financial situation of participants. Taken together, the three findings: diabetes can be prevented, as demonstrated in efficacy trials; diabetes prevention is cost-effective, as shown in cost-effectiveness analysis; and the findings presented in this dissertation that out-of-pocket expenses to participants need not increase in order while participants reduce risk factors for type 2 diabetes, indicate that the economic impact of diabetes might be attenuated through public health programming.

## **7.2 PUBLIC HEALTH SIGNIFICANCE**

This dissertation has rendered a comprehensive assessment and analysis of the experience of individuals participating in several deliveries of the Group Lifestyle Balance (GLB) program [18], a community-delivered diabetes prevention program, translated from the Diabetes Prevention Program (DPP) [13]. It includes quantifiable aspects of program participation as directly experienced by the participant, with a particular focus on health-related quality of life and direct nonmedical, out-of-pocket expenses paid by the participant.

Given estimates of future increase in diabetes in America (from 23.7 million in 2009 to 44.1 million in 2034 [12]), it is imperative that urgent public health action be taken to reduce the risk of diabetes. The DPP behavioral lifestyle intervention on which the GLB is based is noteworthy in that it is one of only a few public health interventions that successfully demonstrated that it is possible to reduce the risk of a disease through behavioral change. It is necessary to continue to build on the DPP legacy and expand delivery of lifestyle intervention programs in diverse community settings in order to help prevent or delay type 2 diabetes and other chronic diseases, including obesity. The impact of the recent classification of obesity as a disease by the American Medical Association[185] remains to be seen, but it is probable that it will continue to increase the demand for programs that teach a healthy lifestyle.

The findings presented in this dissertation should help to reduce some promotional and participatory barriers that community diabetes prevention interventions may experience, particularly surrounding the question of whether it is possible to reduce diabetes risk factors without incurring substantial additional expenses. This dissertation suggests an answer in the affirmative, which will increase the likelihood of making diabetes prevention programming an

attractive option for all individuals, especially those at the lower end of the socioeconomic spectrum who may believe that meaningful lifestyle change is out of reach due to cost.

Independent of a reduction of the clinical risk factors for type 2 diabetes, the fact that individuals may also help maintain or improve their health-related quality of life should also be promoted as a public health benefit of a behavioral lifestyle translation intervention such as the GLB. These findings will help enable prospective participants to make informed decisions about the time and expenses that they should be prepared to commit in order to reduce their diabetes risk, as well as how their quality of life might be affected.

Through much of its natural history [186], type 2 diabetes is asymptomatic. Although some pathologies related to elevated glucose may appear in the prediabetes phase [94], individuals with prediabetes often feel well and thus may not be motivated to take steps to reduce their risk of diabetes. While this is certainly a short sighted perspective, it is nevertheless common, potentially making diabetes less feared than some other diseases and thus reducing the incentive to prevent it. The fact that participants experience improvements in HRQoL, while accruing few additional expenses, should aid in dispelling the myth that diabetes prevention is expensive and that its benefits are intangible or only experienced at some future time.

### **7.3 FUTURE DIRECTIONS**

Type 2 diabetes remains a significant health threat to many in America and around the world. The impact of diabetes is substantial, both to the individual and in terms of the expense to society



at large. It is for these reasons that research must continue into identifying effective and efficient avenues so that diabetes prevention intervention can reach as many individuals as possible.

Paper 1 showed that quality of life improved among participants in a diabetes prevention program. However, it is true that the reported improvements were modest, possibly owing to the fact that at baseline, many of the participants considered themselves to be almost perfectly healthy as measured by widely-used health-related quality of life (HRQoL) assessment tools, including the Euro-Qol (EQ-5D-3L). Recognizing this so-called “ceiling effect,” where a large number of respondents rate themselves at the highest level, a five level version of the instrument (the EQ-5D-5L) has been developed [132] which may allow a greater discrimination in the data collected, and reveal smaller changes in HRQoL that were not detectable with the instruments used in this investigation. Future Group Lifestyle Balance (GLB) investigations should consider using the EQ-5D-3L for evaluating HRQoL.

Although the relationship between weight loss and HRQoL has not been consistent in the published literature, it is generally accepted that weight loss may contribute to improvements in HRQoL. This is a significant consideration for this dissertation because the relationship between weight loss and HRQoL is not yet established in community diabetes prevention settings. While it could be argued that from the participant’s perspective it doesn’t matter whether improved HRQoL resulted from weight loss alone or in combination with other factors, from a research perspective it would be useful to determine whether diabetes prevention interventions are improving HRQoL due to weight loss or whether some other program outcomes are also contributing.

In terms of direct nonmedical expenses research, there are additional questions that remain unanswered. Paper 3 of this dissertation showed that participants can reduce their risk

factors for type 2 diabetes and/or components of the metabolic syndrome while experiencing little change in direct nonmedical expenses. However, whether or not there were significant changes in the actual food items purchased (less junk food, more fruits, vegetables, or whole grains) remains unanswered. Future analyses of itemized food purchase receipts collected as part of this investigation would help answer questions about what food items participants actually purchased and whether purchasing patterns changed during the intervention.

More globally, of the findings in this dissertation, those about participant expenses will likely be of greatest benefit in advancing diabetes prevention activity. It is clear from these results that successful reduction of risk factors for type 2 diabetes can be achieved within the budgetary constraints of a population of primarily white individuals from a socioeconomic range extending from blue collar and higher, including among retirees (see Paper 3). However, whether this finding would hold in a low socioeconomic setting or among a racial or ethnic minority population has yet to be investigated. Future HRQoL analyses, including from participants in a delivery of the Spanish version of the GLB, should be conducted to answer these questions.

While the scientific evidence regarding the expenses of healthy food may be conflicting, there is abundant anecdotal evidence of a perception that a healthy lifestyle, consisting of healthy food and increased physical activity, is more expensive than the less-healthy and sedentary alternatives. It is possible that recruiting efforts may be affected by this perception, even for diabetes prevention programs that do not charge a fee or require insurance billing. However, the extent to which this perception would influence an eligible participant is unknown. Further research should be conducted on how perceptions of expenses affect recruitment success, particularly among lower socioeconomic classes and minority groups.

Lastly, marketing research could help identify the most effective means to promote diabetes prevention efforts as an expense-neutral intervention that can result in important health benefits. The challenge is that there is little profit in disease prevention and thus commercial organizations have little motivation for such research. With the increasing involvement of the Federal government in the health of America through the Affordable Care Act, it is possible that the Centers for Disease Control, National Institutes of Health, or Department of Agriculture may be best suited to promote such a message. The Agricultural Department already is involved in research on food expenses as part of the Thrifty Food Plan [180] and may be well-positioned to take a leadership role in this effort.

The DPP demonstrated that type 2 diabetes can be delayed or prevented in a cost-effective manner [13,154], a finding confirmed in translational studies [156,187]. It is known that diabetes prevention works, however, given the numbers at risk, the magnitude of the challenge can seem daunting. It is likely that additional diabetes prevention efforts in new settings or using novel technology will be shown effective in reducing diabetes risk as long as weight loss, dietary improvement, and increased physical activity are achieved, and such findings are useful additions to the translational literature. However, what is now needed is a concerted effort to prepare and train health professionals how deliver diabetes prevention programs such as the GLB in whatever setting they find themselves. The impact of healthcare reform in America remains uncertain, but what is certain is that, regardless of politics, prevention will have to play a more important role in America's healthcare priorities. Those invested in diabetes prevention must be ready to meet the needs that emerge.

## **APPENDIX A: PAPER 1**

### **Health-Related Quality of Life in a Community Diabetes Prevention Program**

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#### **Abstract**

This study tested the hypothesis that participation in a behavioral lifestyle intervention based on the Diabetes Prevention Program resulted in improved health-related quality of life among 81 participants with prediabetes and/or the metabolic syndrome. Post-intervention, participants reported a significant increase in the number of “healthy days” and days when they “felt very healthy and full of energy,” compared with baseline, as well a decrease in the number of days when they didn’t get enough rest or sleep. These findings show that, beyond improvement in physiological parameters, behavioral lifestyle interventions for diabetes prevention are associated with improvements in quality of life.

#### **Introduction**

Behavioral lifestyle intervention is an effective approach for confronting the public health challenge of diabetes, and has been shown to reduce the risk of type 2 diabetes in several clinical trials (Pan et al., 1997; Ramachandran et al., 2006; Tuomilehto et al., 2001). In particular, the Diabetes Prevention Program demonstrated a 58% reduction in risk for the development of type 2 diabetes (Knowler et al., 2002). Participants in the Diabetes Prevention Program also showed

improvements in health-related quality of life (HRQoL) scores related to physical functioning and vitality (Florez et al., 2012).

Translational research studies based on the Diabetes Prevention Program lifestyle intervention have been successful in reducing risk factors associated with the development of type 2 diabetes in a variety of community settings (Ackermann, Finch, Brizendine, Zhou, & Marrero, 2008; Amundson et al., 2009; Davis-Smith et al., 2007; Katula et al., 2011; Kramer et al., 2009; Kramer et al., 2010; Kramer, McWilliams, Chen, & Siminerio, 2011; McTigue, Conroy, Bigi, Murphy, & McNeil, 2009; Whittemore et al., 2009). It stands to reason that these community diabetes prevention programs would also improve quality of life, but this has not been documented.

It is clear that elevated glucose levels are associated with reduced HRQoL in those with type 2 diabetes (Brown et al., 2004; Schunk et al., 2011). Additionally, non-diabetic individuals with elevated blood glucose concentrations have been found to have reduced HRQoL when compared to those with normal glucose (Chittleborough, Baldock, Taylor, Phillips, & North West Adelaide Health Study, 2006). Reduced HRQoL is also present in individuals at elevated risk for diabetes based on a risk questionnaire, relative to age and gender weighted population norms (Hakkinen et al., 2009). Likewise, individuals with the metabolic syndrome, a condition that includes elevated blood glucose as a diagnostic criterion, have been shown to have lower HRQoL than those without the metabolic syndrome (Ford & Li, 2008; Miettola, Niskanen, Viinamaki, Sintonen, & Kumpusalo, 2008).

In contrast, very little has been published with regard to change in HRQoL among participants in community prevention programs targeting type 2 diabetes and/or the metabolic syndrome. A Korean study demonstrated that a lifestyle modification program resulted in

significant improvements in the HRQoL of female participants with the metabolic syndrome (Oh et al., 2010). In Brazil, a program to improve quality of life and reduce depression and binge eating disorder among individuals with prediabetes or the metabolic syndrome also reported improved HRQoL (Cezaretto, Siqueira-Catania, de Barros, Salvador, & Ferreira, 2012). These findings suggest that HRQoL may be influenced by community programs targeting the prevention of diabetes and the metabolic syndrome.

Even though the effectiveness of behavioral lifestyle interventions for reducing risk of type 2 diabetes is well established, the impact of these programs on HRQoL is still emerging. Thus, the purpose of the current effort was to test the hypotheses that a community lifestyle intervention based on the Diabetes Prevention Program and administered by diabetes educators resulted in improved HRQoL among the participants, and that baseline HRQoL predicted success in attaining specific program goals.

## **Methods**

The Group Lifestyle Balance program (Kramer et al., 2009) is a behavioral lifestyle intervention adapted from the Diabetes Prevention Program. The Group Lifestyle Balance curriculum includes a weight loss goal of 7% and a target of 150 minutes per week of moderately intense physical activity. These goals were successfully used in the Diabetes Prevention Program to decrease the risk of developing type 2 diabetes (Knowler et al., 2002) and reduce cardiovascular disease risk factors (Orchard et al., 2005). The Group Lifestyle Balance program has been successfully implemented in a variety of settings, including medically underserved communities, clinical practices, a fitness center, and churches (Dodani & Fields, 2010; Kramer et al., 2009; McTigue et al., 2009; Seidel, Powell, Zgibor, Siminerio, & Piatt, 2008).

The current study is a non-randomized, single-group, evaluation of implementation of the Group Lifestyle Balance program, with outcome variables assessed at baseline, post-intervention (about four months), and at six and 12 months. Diabetes educators trained to deliver the Group Lifestyle Balance program presented the intervention over 12-14 weeks, in groups of 7-16 participants at three outpatient diabetes education program sites in Western Pennsylvania, operated by the University of Pittsburgh Medical Center. The study protocol was approved by the University of Pittsburgh Institutional Review Board and all study participants provided informed consent. A detailed description of the study design, setting, and interventionist training, as well as participant recruitment, has been published elsewhere (Kramer et al., 2011) and is summarized below.

#### Eligibility and recruitment

Individuals at least 25 years old, with a body mass index (BMI)  $\geq 25$  kg/m<sup>2</sup>, and no previous diabetes diagnosis were eligible to participate when meeting the criteria for prediabetes (fasting plasma glucose 100-125 mg/dl) (American Diabetes, 2004) and/or the metabolic syndrome. The metabolic syndrome was defined following the National Cholesterol Education Program Adult Treatment Panel 3 criteria as a clustering of abdominal obesity, atherogenic dyslipidemia, hypertension, and insulin resistance. Diagnostically, the metabolic syndrome is determined by the presence of three or more of these five conditions: 1. elevated triglycerides ( $\geq 150$  mg/dl), 2. low HDL cholesterol ( $< 40$  mg/dl for men,  $< 50$  mg/dl for women), 3. increased waist circumference ( $> 102$  cm for men,  $> 88$  cm for women), 4. blood pressure  $\geq 130/85$  mm Hg (or on treatment for hypertension), 5. elevated fasting plasma glucose ( $\geq 100$  mg/dL) (Expert Panel on Detection & Treatment of High Blood Cholesterol in, 2001). For the current study, individuals previously diagnosed with diabetes, pregnant or lactating women (within past six

weeks), individuals unable to obtain physician referral to engage in moderate physical activity, or persons planning to leave the area before the end of the study, were ineligible.

Recruitment involved the utilization of existing referral networks of primary and specialist physicians, direct mail and e-mail to physician practices, community posters, and local print media. A total of 121 physician referrals were received, with 95 individuals meeting eligibility criteria and 81 (85.3%) enrolling in the program.

### Outcomes

Primary outcomes published elsewhere include change in weight and physical activity levels, with secondary outcomes of glucose, HDL cholesterol, LDL cholesterol and triglyceride levels, abdominal obesity and hypertension status (Kramer et al., 2011). HRQoL, measured using the CDC Health-Related Quality of Life-14 Healthy Days Measure was also a secondary outcome of this study.

### CDC Health-Related Quality of Life-14 Healthy Days Measure

The CDC HRQoL–14 Healthy Days Measure (CDC HRQoL) assesses self-reported health (Moriarty, Zack, & Kobau, 2003). It consists of four core questions about general health and the number of unhealthy days during the past 30 days, followed by ten questions about recent pain, depression, anxiety, sleeplessness, or vitality; and the cause, duration, and severity of any current activity limitation. The CDC HRQoL was completed at each assessment visit.

### Data analysis

Data from those participants who attend the assessment visits were included in the analyses. Within this group, analysis for each question used available data. This may result in unequal sample sizes for HRQoL question due to missing data. Fisher's Exact Test was used for comparing sets of categorical variables and McNemar's Test for the change of categorical



variables pre- to post-intervention. To compare continuous variables, the paired t-test was used if the variable was normally distributed, and the signed rank test when the distribution was not normal.

For the CDC HRQoL, self-reported health, unhealthy days, and a post-intervention report of a new major impairment or health problem that limited activities were investigated as predictors of Group Lifestyle Balance program outcomes. Three distinct outcomes were investigated: First, whether the participant attended 50% or more of the 12 weekly intervention sessions; second, whether 5% or greater weight loss was attained at the end of the 12-week intervention; and third, whether the participants reported 150 minutes or more physical activity at the post-intervention visit. The 5% criterion for weight loss is based on a recent report that adaptations of the DPP achieved clinically significant weight loss of approximately 5% (Ali et al., 2012). Health was considered “good” when the participants reported that in general, their health was excellent, very good, or good; and “not good” when they reported that in general, their health was fair or poor.

An “unhealthy days” measure was created, consisting of the sum of days when reported physical or mental health was not good during the past 30 days. Combining the days on which physical and mental health were not good is an approach recommended by the CDC for HRQoL analysis (Centers for Disease & Prevention, 2000), and has been validated (Newschaffer, 1998). Dichotomous variables for “unhealthy days” (which includes physical and mental health) and “frequent mental distress” (mental health only) were based on whether the individual reported 14 or more unhealthy days in the preceding categories during the past month. Analyses were carried out using the SAS statistical package (version 9.3, SAS Institute, Cary North Carolina, USA).

## Results

Study participants were predominantly female (88%) and white (96%), with 52% having a family history of diabetes and 63% having a family history of heart disease (Table A.1). Almost half (49%) of the participants had prediabetes at baseline.

**Table A.1 Baseline Participant Characteristics**

	Male 12% (n=10) % (n)	Female 88% (n=71) % (n)	Total (n=81) (n, %)
Average age (range)	52.3 (39-66)	53.0 (26-80)	52.9 (26-80)
White	90 (9)	97 (69)	96 (78)
Employed full/part time	60 (6)	76 (54)	74 (60)
Education			
High School/GED	10 (1)	24 (17)	22 (18)
Some college/tech school	50 (5)	45 (32)	46 (37)
College graduate	10 (1)	17 (24)	22 (18)
Graduate degree	30 (3)	7 (5)	10 (8)
Smoking	10 (1)	8 (6)	9 (7)
Family History			
Diabetes	40 (4)	54 (28)	52 (42)
Heart Disease	2 (20)	69 (49)	63 (51)
Prediabetes	60 (6)	48 (34)	49 (40)

Source (Kramer et al., 2011)

Self-reported health (“good” versus “not good”) was examined over the course of the year among those who attended all assessment visits (n=43). At the 4-month post-intervention assessment, there appeared to be an increase (from 81% to 95%  $p=0.07$ ) in those reporting “good” health (Table A.2), compared to baseline.

**Table A.2 Comparison of Baseline Scores for Self-Assessed Health in General With Follow-Up at Post-Intervention, Six Months, and 12 Months Among Completers (n=43)**

	Health in General “good” <sup>1</sup> n (%)	Health in General “not good” <sup>2</sup> n (%)	<i>p</i> (compared with baseline)
Baseline	81 (35)	19 (8)	
Post-Intervention (4 months)	95 (41)	5 (2)	0.07
Six Months	91 (39)	9 (4)	0.29
12 Months	91 (39)	9 (4)	0.22

<sup>1</sup> participants who reported health in general as excellent, very good, or good

<sup>2</sup> participants who reported health in general as fair or poor

Over the course of intervention, there was a decrease in the number of participants who reported that they did not get enough rest or sleep (10.7% to 6.3%,  $p=0.002$ ) (Table A.3). Significant improvements in rest and sleep remained at six and 12 months from baseline. In addition, at four months there was an increase in the number of days when the participants reported that they “felt very healthy and full of energy” (11.0% to 14.9%,  $p=0.02$ ), with this change remaining significant at six months. The other HRQoL components were not significantly changed from baseline to post-intervention. Stratifying by gender did not change the results among females, although likely due to the small sample size ( $n=10$ ), there were no significant changes from pre to post intervention among males.

**Table A.3 HRQoL Measures Pre- and Post-Intervention (approx. 4 months) Among Completers (n=68)**

Parameter	n	Pre	Post	Change	<i>p</i>
Mean Unhealthy Days	53	7.4	7.7	0.3	0.96
% with Unhealthy Days $\geq 14$	53	24.5% (13)	20.8% (11)	-3.7	0.79
Mean Physically Unhealthy Days	61	2.9	3.0	0.1	0.82
Mean Mentally Unhealthy Days	57	4.4	5.0	0.6	0.42
% With Frequent Mental Distress	57	17.5% (10)	10.5% (6)	-7.0	0.29
Mean Days When Poor Mental or Physical Health Limited Activities	64	2.0	2.1	0.1	0.39
% Limited in Activities because of Impairment or Health Problem	67	64.2% (43)	56.7% (38)	-7.5	0.23
Mean Days Pain Inhibited Usual Activities	60	2.8	3.4	0.6	0.24
Mean Days Sad or Depressed	60	2.9	3.4	0.5	0.56
Mean Days Worried or Anxious	54	5.0	4.3	-0.7	0.52
<b>Mean Days Felt Did Not Get Enough Rest or Sleep</b>	<b>55</b>	<b>10.7</b>	<b>6.3</b>	<b>-4.4</b>	<b>0.0002<sup>a,b</sup></b>
<b>Mean Days Felt Very Healthy and Full of Energy</b>	<b>50</b>	<b>11.0</b>	<b>14.9</b>	<b>3.9</b>	<b>0.02<sup>a</sup></b>

<sup>a</sup> Remained significant ( $p \leq 0.05$ ) at six months

<sup>b</sup> Remained significant ( $p \leq 0.05$ ) at 12 months

Participants for whom the number of unhealthy days in the past month was less than 14 were significantly more likely to have attended 50% or more of the sessions than those who

reported 14 or more unhealthy days ( $p=0.001$ ). Self-reported health approached significance ( $p=0.068$ ) in predicting Group Lifestyle Balance program success, as measured by session attendance of 50% or greater (Table A.4). The use of the HRQoL measure for “baseline unhealthy days” appeared to predict self-reported achievement of the 150 minute per week activity goal at four months for those having less than 14 unhealthy days, although this finding was of borderline significance ( $p=0.077$ ).

At the four-month post-intervention assessment, 18 participants reported a new major impairment or health problem that limited their activities: nine participants reported impairments related to walking, fractures, or bone/joint injury; three reported arthritis/rheumatism; two reported back or neck problems; two reported depression, anxiety, or emotional problems; while one each reported heart problems and “don’t know or unsure.” Reports of these health problems did not predict attainment of Group Lifestyle Balance outcome goals

**Table A.4 Baseline HRQoL measures and Group Lifestyle Balance attendance, weight loss, and self-reported activity at 4 months.**

	Baseline Self-Reported Health in General			Baseline Unhealthy Days <sup>3</sup>			Major Impairment at 12 Weeks, Among Participants Who Had None at Baseline <sup>4</sup>		
	“good” <sup>1</sup> (n=57) % (n)	“not good” <sup>2</sup> (n=20)	<i>p</i>	<14 in past month (n=46)	>=14 in past month (n=24)	<i>p</i>	No (n=58)	Yes (n=10)	<i>p</i>
attend>= 50% of sessions	90 (51)	70 (14)	0.068	94 (43)	67 (16)	0.001	98 (57)	100 (10)	1.000
attained >=5% weight loss	40 (23)	55 (11)	0.302	50 (23)	38 (9)	0.124	52 (30)	30 (3)	0.307
achieved >=150 minutes self-reported physical activity per week at 4 months	(n=50) 48 (24)	(n=12) 4 (33)	0.521	(n=42) 55 (23)	(n=15) 27 (4)	0.077	(n=55) 46 (25)	(n=10) 50 (5)	1.000

<sup>1</sup>participants who reported health in general as excellent, very good, or good

<sup>2</sup>participants who reported health in general as fair or poor

<sup>3</sup>cumulative measure of physically and mentally unhealthy days in the past month

<sup>4</sup>reported post-intervention: “what is the major impairment or health problem that limits your activities?”

**Table A.5 HRQoL Measures Pre-and Post-Intervention (approx. 4 months) Among Completers Stratified by Gender (n=68).**

Male						Female					
Parameter	n	Pre	Post	Change	<i>p</i>	n	Pre	Post	Change	<i>p</i>	<i>p between</i>
Mean Unhealthy Days	8	6.8	8.8	2	0.56	45	7.5	7.5	0	0.99	0.75
% with Unhealthy Days ≥14	8	25.0% (2)	25.0% (2)	0	1.0	45	24.4% (11)	20.0% (9)	-4.4	0.77	
Mean Physically Unhealthy Days	9	2.2	1.3	-0.9	0.81	52	3.1	3.3	0.2	0.88	0.84
Mean Mentally Unhealthy Days	9	6.0	10.6	4.6	0.37	48	4.1	4.0	-0.1	0.71	0.71
% With Frequent Mental Distress	9	33.3% (3)	33.3% (3)	0	1.0	48	14.6% (7)	6.3% (3)	-8.3	0.22	
Mean Days When Poor Mental or Physical Health Limited Activities	10	3.3	1.0	-2.3	1.0	54	1.7	2.3	0.6	0.20	0.14
% Limited in Activities because of Impairment or Health Problem	10	80.0% (8)	70.0% (7)	-10.0	1.00	57	61.4% (35)	54.4% (31)	-7.0	0.34	
Mean Days Pain Inhibited Usual Activities	10	0.3	0.9	0.6	1.0	50	3.3	3.9	0.6	0.33	0.59
Mean Days Sad or Depressed	10	4.9	6.8	1.9	1.0	50	2.4	2.7	0.3	0.50	0.97
Mean Days Worried or Anxious	10	4.7	7.2	2.5	1.0	44	5.1	3.6	-1.5	0.41	0.58
<b>Mean Days Felt Did Not Get Enough Rest or Sleep</b>	9	7.1	3.1	-4.0	0.16	<b>46</b>	<b>11.4</b>	<b>6.9</b>	<b>-4.5</b>	<b>0.01</b>	0.95
<b>Mean Days Felt Very Healthy and Full of Energy</b>	8	14.3	14.3	0	0.81	<b>42</b>	<b>10.4</b>	<b>15.0</b>	<b>4.6</b>	<b>0.02</b>	0.47

## Discussion

Individuals with prediabetes and/or the metabolic syndrome who participated in a community diabetes prevention intervention experienced positive changes in several Quality of Life domains over the course of the intervention. In addition, HRQoL was associated with participant success in achieving some of the program goals. These results demonstrate that there are benefits to community diabetes prevention programs that extend beyond improvement in the physiological parameters typically measured. It also suggests that the quality of life of participants at baseline may impact the likelihood that they will achieve some of the program goals.

There was a suggestion of an increase in the number of participants who described the state of their health as “good” rather than “not good” at the end of the intervention relative to baseline. Oh and colleagues (Oh et al., 2010) showed similar results, finding an increase in the general health domain of the SF-36 following a six month lifestyle modification program among Korean women with the metabolic syndrome. Likewise, Levinger and colleagues (Levinger, Goodman, Hare, Jerums, & Selig, 2007) reported a significant increase in self-reported general health on the SF-36 survey among those with a high number of metabolic risk factors taking part in a 10-week resistance training program. Although these earlier studies used the SF-36 HRQoL survey, the CDC HRQoL has acceptable criterion validity when compared to the SF-36 (Newschaffer, 1998), suggesting that the results from both instruments are likely comparable. This finding of improved self-reported general health demonstrates a benefit of these behavioral lifestyle programs to the participant that is not usually assessed in a standard clinical visit.

At the post-intervention visit, participants reported a significant decrease in the number of days that they did not get enough rest or sleep, and an increase in the number of days they felt



very healthy and full of energy. There was also a significant decrease in those reporting fair or poor health, similar to unpublished findings from an earlier Group Lifestyle Balance intervention (Kramer, 2009). These results again strengthen the case that HRQoL improves among participants in a diabetes prevention program.

Baseline HRQoL measures successfully predicted participant success in meeting some Group Lifestyle Balance goals. Those who had less than 14 unhealthy days in the past month were more likely to have attended at least six of the 12 sessions, when compared to those with 14 or more unhealthy days. Those with fewer unhealthy days were also more likely to achieve the weekly physical activity goals of 150 or more minutes, with borderline significance. This finding is not surprising. Participants who feel healthier would likely be more inclined to attend the weekly sessions as well as be more active. This use of HRQoL scores as a predictor of participant success in meeting program outcomes has not been widely reported. Recently, Beck and Shah examined changes in HRQoL in a variety of settings to predict cardiac outcomes, with improved HRQoL found to be a significant predictor of event-free survival (Beck & Shah, 2012). In the future, baseline HRQoL could be used to identify participants who are at elevated risk of not meeting the program goals, and extra measures could be taken to help ensure their success.

It is not obvious why the number of unhealthy days predicts attendance while “self-reported health in general” is only a marginally significant predictor. It is possible that participants found it easier to numerically quantify days when physical and mental health are not good, than to make the more absolute statement that their health is “fair” or “poor.” It is also possible that those who are feeling well may stop attending the classes because they believe that they have benefitted enough from the program at that point, reducing the difference in attendance between the two groups.

It was anticipated that the emergence of new major impairments or health problems over the course of the intervention would impact session attendance and the attainment of weight loss and activity goals. However, attendance was clearly not affected by new impairments, with close to 100% of both those with and without impairments attending 50% or more of the sessions. The fact that neither attendance nor physical activity were affected by new physical impairments suggests that many of the impairments may not have been serious enough to limit mobility. Additionally, as there were only 10 participants with new impairments, the finding of no difference between the impaired and not-impaired groups may be related to sample size.

The Group Lifestyle Balance program is not specifically a weight loss or physical activity program, however, diabetes risk reduction is achieved through the prescription of calorie and activity goals that result in weight loss. While lifestyle intervention programs have been shown to improve quality of life among those with the metabolic syndrome, other research suggests that the metabolic syndrome may not be independently associated with impaired HRQoL, and that obesity and depression may have a more important impact on HRQoL (Vetter et al., 2011). The Diabetes Prevention Program also found that weight loss accounted for HRQoL benefits (Florez et al., 2012). Additionally, it has been shown that among individuals with prediabetes, quality of life is higher among those who are physically active compared to those who are not (Taylor et al., 2010) and that HRQoL declines linearly with decreasing physical activity (Hakkinen et al., 2009). It is thus possible that improvements in quality of life in this study resulted from weight loss, increased physical activity, or a combination of those factors, and are not a consequence of decreases in other diabetes risk factors.

There are several limitations with this study. This was a non-randomized, single-group prospective design with a modest sample size. Generalizability is limited in that the population

was primarily Caucasian. Participant physical activity was self-reported and not objectively measured. Additionally, it is possible that having the lifestyle intervention implemented by diabetes educators with advanced training in self-management strategies could bias the results.

## **Conclusions**

The findings of this study show that beyond improvement in physiological parameters, behavioral lifestyle interventions for diabetes prevention can improve quality of life. These benefits serve to bolster the case for diabetes prevention as a vital public health endeavor, because those who participate not only reduce their risk for diabetes, but their quality of life also improves, and they feel better. This study also points the way to an approach which uses baseline HRQoL to identify participants at increased risk of not meeting intervention goals, allowing them to receive targeted or individual attention. The continuing use of HRQoL assessment will expand the view of what health is, as well as identify novel benefits of diabetes prevention programs.

**Declaration of Conflicts of Interest:** None

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## **APPENDIX B: PAPER 2**

### **Health-Related Quality of Life in a Diabetes Prevention Intervention Presented in Groups and Via DVD**

#### **Introduction**

Elevated blood glucose is associated with decreased health-related quality of life (HRQoL) relative to individuals with normal glucose. This finding holds whether diabetes is present [1,2] or not [3,4]. The presence of the metabolic syndrome is also associated with reduced HRQoL [5,6]. As elevated blood glucose and the metabolic syndrome are both associated with lower HRQoL, it follows that reducing risk factors for these conditions could improve HRQoL.

In addition to lowering risk for diabetes, the Diabetes Prevention Program (DPP) [7], showed that participants in a behavioral lifestyle intervention also had improved HRQoL in general health, physical function, body pain, and vitality [8]. Whether participants in community DPP-based translational research projects experience similar improvements in HRQoL has not yet been documented.

This effort evaluated HRQoL among participants in the Group Lifestyle Balance (GLB) program, a community translation of the DPP lifestyle intervention. Specifically, it tested the hypothesis that participants in a translational behavioral lifestyle intervention that resulted in significantly improved lifestyle behavior and clinical measures, also experienced improvements in HRQoL.

## Methods

The GLB program [9] was adapted from the DPP lifestyle intervention by the Diabetes Prevention Support Center (DPSC) of the University of Pittsburgh. Typically delivered in a group format, this investigation pilot tested a DVD version of the program. The group version has been successfully implemented in a variety of settings [10-12]. The design and methods for this investigation are reported elsewhere [13] and summarized here.

### Setting, Recruitment, and Eligibility

Health care providers at a primary care practice referred non-diabetic patients aged 18 or older, with a body mass index (BMI)  $\geq 25$ , along with prediabetes [14] and/or the metabolic syndrome [15], to the intervention.

### Program Delivery

Participants selected either a group setting or DVD for program delivery. Group participants attended 12 sessions, delivered over 12-15 weeks by a nurse practitioner trained by the DPSC to deliver the program. DVD participants attended one session with the nurse practitioner for an overview of the program and materials, and viewed the first DVD. DVD participants viewed one session weekly, with weekly telephone contact from a lifestyle coach at the DPSC to review weight, physical activity minutes, and any questions. Participants in both group and DVD delivery modes were thus offered 12 professional contacts. Participants received a GLB workbook, fat and calorie counter, pedometer, and self-monitoring books for tracking weight, food intake and physical activity. Clinical assessment visits occurred at baseline, and post-intervention (approximately 3 months), six, and 12 months from baseline.

The Institutional Review Board at the University of Pittsburgh and the Western Institutional Review Board approved this investigation. All participants provided informed consent.



## Outcomes

The primary outcome was weight loss. Secondary outcomes included waist circumference, BMI, cholesterol, fasting glucose, HbA1C, blood pressure, triglycerides, and self-reported physical activity. Participants completed the EuroQol EQ-5D-3L™ at each assessment visit.

### EuroQol EQ-5D-3L™ (EQ-5D and Visual Analogue Scale (VAS))

The EQ-5D-3L™ HRQoL-assessment questionnaire consists of two parts: the EQ-5D and the Visual Analogue Scale (VAS). For the EQ-5D, participants indicated their impairment in each of five health dimensions by choosing one of three levels, equivalent to “none,” “moderate,” and “extreme.” A summary EQ-5D index score was calculated, using an algorithm available from EuroQol ([www.euroqol.com](http://www.euroqol.com)). Index scores range from 0 to 1. Higher values indicate better HRQoL.

The Visual Analogue Scale (VAS) resembles a thermometer marked 0-100, on which participants reported their current health state. Zero represents the “worst imaginable health state” and 100 the “best imaginable health state.”

### HRQoL Data Analyses

Analyses were conducted: 1. On an intention-to-treat basis, with the last observation carried forward for missing data; 2. Limited to those who attended the six-month clinical visit and whose baseline index score was less than the US adult average; and 3. Including only those who attended all four clinical visits. The paired t-test was used to test before/after differences of normally distributed EQ-5D index and VAS values, and the Wilcoxon signed-rank test for non-normal distributions. The Spearman rank-order correlation was used to test associations between weight loss and HRQoL. Analyses were performed using SAS 9.3.

## **Results**

The 48 participants enrolled in this study were predominantly female (34 female, 14 male) and white (83%), and had a mean age of 59.7 years (Table B.1); 22 chose DVD and 26 selected group delivery.

**Table B.1 Participant Baseline Characteristics**

	Total n=48 n (%)
Age mean (range)	59.7 (22-87)
Female	34 (71)
White	40 (83)
Employed full/part time	25 (52)
Highest Education	
Some High School or Lower	3 (6)
High School/GED	10 (21)
Some college/tech school	16 (33)
College graduate	11 (23)
Graduate degree	8 (17)
Smoker	1 (2)
Family History	
Diabetes	25 (52)
Heart Disease	24 (50)

At three months, there were significant improvements in weight, waist circumference, BMI, HbA1C, and systolic blood pressure among participants in both delivery groups, as well as significant increases in self-reported physical activity [13]. At baseline, the median EQ-5D index score was 0.83 (Table B.2). No significant changes occurred in the EQ-5D index scores at three, six, and 12 months, compared to baseline. This finding remained constant when participants in the two delivery methods were combined, and when they were analyzed separately. Among those participants who attended all four assessments (n=31), there were no significant changes in the EQ-5D index scores at three, six, and 12 months, compared to baseline (results not shown). However, when limiting the analyses to only those participants whose baseline EQ-5D index scores were below the US average value of 0.87 [16] and who attended the three month assessment (Table B.2, bottom) (n=27), there was an increasing trend in median index score at three months (p=0.07).

**Table B.2 EQ-5D Index Scores<sup>1</sup>**

All Participants							
	Baseline	3 Months	<i>p (with baseline)</i>	6 Months	<i>p (with baseline)</i>	12 Months	<i>p (with baseline)</i>
<i>Group and DVD</i>							
<i>Combined:</i>	(n=45 )						
<i>median</i>	0.83	0.83	0.43	0.83	0.78	0.83	0.70
<i>25<sup>th</sup></i>	0.78	0.80		0.80		0.80	
<i>75<sup>th</sup></i>	0.84	1.00		0.84		0.84	
<i>DVD only:</i>	(n=21)						
<i>median</i>	0.84	0.83	0.56	0.83	0.41	0.83	0.39
<i>25<sup>th</sup></i>	0.82	0.81		0.81		0.81	
<i>75<sup>th</sup></i>	1.00	1.00		1.00		1.00	
<i>Group only:</i>	(n=24)						
<i>median</i>	0.80	0.83	0.11	0.81	0.31	0.83	0.88
<i>25<sup>th</sup></i>	0.77	0.80		0.79		0.76	
<i>75<sup>th</sup></i>	0.83	0.84		0.84		0.84	
Participants whose baseline score was less than or equal to US adult mean of 0.87 [16]							
	Baseline	3 Months	<i>p (with baseline)</i>	6 Months	<i>p (with baseline)</i>	12 Months	<i>p (with baseline)</i>
<i>Group and DVD</i>							
<i>Combined:</i>	(n=27 )						
<i>median</i>	0.81	0.82	0.07	0.81	0.31	0.80	0.79
<i>25<sup>th</sup></i>	0.77	0.80		0.80		0.76	
<i>75<sup>th</sup></i>	0.83	0.83		0.84		0.84	

1. EQ-5D Index Score is a composite of the five quality of life dimensions. 0=poorest health, 1=best health

The median baseline VAS score for all participants was 70. During the intervention, significant increases occurred in the median participant VAS scores at each clinical visit, relative to baseline (Table B.3), with the VAS score increasing to 80 at the three and six month assessments, and 85 at 12 months. These increases remained significant when analyzing group or DVD delivery individually. The median baseline VAS score of 65 increased to 80 ( $p<0.0001$ ), 79 ( $p<0.0001$ ), and 80 ( $p=0.0011$ ) at 3, 6, and 12 months post-intervention, respectively, when analyses were limited to participants with baseline VAS scores below 79.2, which is the average value reported in the nationally representative Medical Expenditure Panel Survey [17]. Spearman rank order correlations between weight change and VAS change were significant at 3 months ( $\rho=0.43$ ,  $p=0.004$ ), marginally significant at 6 months ( $\rho=0.29$ ,  $p=0.061$ ) and not significant at 12 months ( $\rho=0.18$ ,  $p=0.24$ ).

**Table B.3 EQ-VAS Scores<sup>1</sup>**

	Baseline	3 Months	<i>p (with baseline)</i>	6 Months	<i>p (with baseline)</i>	12 Months	<i>p (with baseline)</i>
<i>Group and DVD Combined:</i>							
<i>median</i>	(n=43) 70	80	<0.01	80	<0.01	85	<0.01
25 <sup>th</sup>	59	70		70		70	
75 <sup>th</sup>	80	85		90		90	
<i>DVD only:</i>	(n=21)						
<i>median</i>	75	80	0.01	80	<0.01	85	0.01
25 <sup>th</sup>	65	75		75		80	
75 <sup>th</sup>	85	90		90		90	
<i>Group only:</i>	(n=22)						
<i>median</i>	67.5	80	<0.01	77	0.03	82.5	0.02
25 <sup>th</sup>	50	70		60		70	
75 <sup>th</sup>	77	80		85		90	

1 EQ-VAS Score summarizes self-reported health on day administered. 0=worst imaginable health, 100=best imaginable health

## Discussion

In this study, despite successfully making lifestyle improvements, there was no significant change in EQ-5D index scores among study participants as a whole. However, the median EQ-5D index score for all participants in this study was 0.83 at baseline, versus an average of 0.87 for US adults [16], suggesting that quality of life within the study group was not significantly impaired. When analyses were limited to the subset of participants with below-average HRQoL at baseline, EQ-5D scores appeared to improve during the intervention.

Measured by the EQ-VAS, participants in this effort showed improvement in HRQoL at three, six, and 12 months. There is no standard Minimally Important Difference (clinically significant value) for those with prediabetes, however values for other conditions range from 7-12 [18,19]. It is thus likely that the EQ-VAS increases found here, ranging from 5-13, signify a meaningful improvement in HRQoL. As with the EQ-5D findings, greater improvement in VAS occurred among those whose baseline VAS scores were below average at baseline. Weight loss alone cannot account for these improvements, as the correlation between HRQoL change and weight loss, while significant at three months, decreased thereafter, was not significant at 12 months.

While not a diabetes prevention intervention, Oh *et al* reported improved HRQoL assessed by the Medical Outcome Study Short Form-36 (SF-36) in a lifestyle intervention for middle aged women with the metabolic syndrome, relative to the control group [20]. Similar results were obtained by Cezaretto *et al* in a lifestyle intervention program for individuals with prediabetes or the metabolic syndrome. They reported significant improvements in most of the SF-36 domains for the intensive lifestyle intervention group, compared to baseline, with greater improvement in the intervention group than the control [21]. These findings are consistent with those reported in the current study, although measured by a different assessment instrument. Participants in both of the above-mentioned studies and the current effort were mostly female and similar age as participants in this effort. The inconsistent change in EQ-5D and EQ-

VAS reported here, was also noted in the Swedish Björknäs study among an intervention population of similar age, although with greater gender balance [22].

A lack of demographic diversity is a limitation of the current study, as is the small sample size, which weakens the ability to detect differences between study subgroups. However the findings suggest HRQoL-improvement among those that were low at baseline. Building on these results, future studies should further explore relationships between HRQoL and specific clinical and behavioral outcomes in translational diabetes prevention programs.

With the physiologic benefits of type 2 diabetes risk reduction through lifestyle change well established in clinical [7,23 ] and translational settings [9,11,13,24,25], these findings help strengthen the case for increasing the use of HRQoL assessment tools in community lifestyle interventions. Recognizing Quality of Life as a tangible and experiential outcome of diabetes prevention programs should assist clinicians and researchers in moving beyond a consideration of isolated physiologic measures, toward an increasingly holistic view of health.

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## **APPENDIX C: PAPER 3**

### **Participant Expenses in a Translational Diabetes Prevention Program**

#### **Introduction**

The Diabetes Prevention Program (DPP) [1] and translational programs based on the lifestyle intervention used in the DPP [2-6] have been shown effective in reducing risk factors for type 2 diabetes. These programs have also demonstrated long term cost-effectiveness [7-10]. However, from the perspective of a potential participant, the cost or expense of most direct interest may not be long-term program cost-effectiveness. Instead, it may be the more immediate expenses that are paid out-of-pocket in order to participate in the program, or the time that is necessary to devote to such a program. These nonmedical expenses are detailed in a review of the societal costs related to type 2 diabetes prevention [11], and include time spent on intervention-related activities such as involvement in physical activity, or self-monitoring of food and beverage intake that would otherwise be spent on a different activity, known as opportunity cost; food costs related to achieving dietary goals; physical activity costs for equipment and services related to physical activity goals; and travel costs for intervention-related visits.

The DPP reported on these nonmedical expenses for both lifestyle participants and a placebo group for three years following the baseline visit [12]. Over three years, per capita food expenses were \$71 less in the lifestyle group compared to the placebo, due to lower expenses for

food purchased away from home. This and higher expenses for physical activity equipment and services like gym memberships or personal trainers, contributed to total expenses that were \$1445 (9.2%) higher per capita in the lifestyle group than placebo over three years.

Additionally, the lifestyle group spent a modestly greater amount of time and had higher transportation expenses related to attending intervention sessions than did the placebo group. These results suggest somewhat greater expenses overall in the lifestyle intervention group than in the placebo group.

While numerous translational diabetes prevention interventions based on the DPP have reported clinical results, there has been only one report of direct nonmedical expenses from such translational programs. The Healthy Living Partnerships to Prevent Diabetes (HELP PD) [13] trial reported expenses results consistent with the DPP findings: higher intervention group expenses due to the expense of time spent in self-monitoring, physical activity, and travel costs related to the intervention, compared to the usual care group, and slightly lower food costs.

The report of per capita expenses in the DPP and HELP-PD trials showed trends of expenditures for the lifestyle and placebo groups, although the statistical significance of these results is unknown. In order to build on the findings of these trials, this current effort will examine participant expenses from baseline to six months and between intervention and control groups after six months of intervention, in a clinical trial within a typical community setting to see if these trends are significant.

## **Methods**

The Group Lifestyle Balance (GLB) program [2] is a behavioral lifestyle intervention adapted from the Diabetes Prevention Program, and typically delivered by trained healthcare

professionals. The curriculum includes the same weight loss goal of 7% and target of 150 minutes per week of moderately intense physical activity that were successfully used in the DPP lifestyle intervention. The GLB program has been successfully implemented in a variety of settings, including medically underserved communities, clinical practices, a fitness center, and churches [2,14-16]

Potential participants were recruited from three community centers using membership communications, direct mail, and posters. Preliminary telephone or in-person screening preceded on-site clinical assessment of eligibility.

Individuals at least 25 years old, with a body mass index (BMI)  $\geq 24$  kg/m<sup>2</sup> for whites and  $\geq 22$  kg/m<sup>2</sup> for Asians, and no previous diabetes diagnosis were eligible to participate when meeting the criteria for prediabetes (fasting plasma glucose 100-125 mg/dl) [17] and/or the metabolic syndrome. The metabolic syndrome was defined following the National Cholesterol Education Program Adult Treatment Panel 3 criteria as a clustering of abdominal obesity, atherogenic dyslipidemia, hypertension, and insulin resistance. Diagnostically, the metabolic syndrome is determined by the presence of three or more of the following five conditions: elevated triglycerides ( $\geq 150$  mg/dl); low HDL cholesterol ( $< 40$  mg/dl for men,  $< 50$  mg/dl for women); increased waist circumference ( $> 102$  cm for men,  $> 88$  cm for women); blood pressure  $\geq 130/85$  mm Hg (or on treatment for hypertension); elevated fasting plasma glucose ( $\geq 100$  mg/dL) [18]. Individuals previously diagnosed with diabetes, pregnant or lactating women (within past six weeks), individuals unable to obtain physician referral to engage in moderate physical activity, or persons planning to leave the area within 18 months, were ineligible.

A delayed control study design was used, with two thirds of participants randomized to an immediate intervention group, and one third randomized to a delayed control group, which

received general health information during the first six months. After six months, the delayed control group received the identical intervention as the immediate group did, offset by six months. This design is ideal in that it provides a randomized comparison group during the first six months of the study when the immediate intervention group receives the majority of the intervention sessions or doses, while at the same time meeting the ethical imperative to eventually offer an effective risk reduction intervention to all participants, all of whom are at elevated risk for type 2 diabetes and/or have the metabolic syndrome.

Participants attended clinical assessment visits at their community enrollment site at baseline and approximately every six months. Clinical variables collected included blood lipids, insulin, fasting plasma glucose, and HbA1c as well as anthropometric measures. A brief medical history was taken and as a series of surveys given.

In order to assess direct nonmedical expenses of participants in this intervention, the participants completed an expenses survey on which they were asked about their estimated time and out-of-pocket expenses related to participating in the GLB intervention, including activity and household food expenses, over the previous six months. These expenses survey was derived in part from the NHANES Flexible Consumer Behavior Questionnaire [19]. The study protocol was approved by the University of Pittsburgh Institutional Review Board and all study participants provided informed consent.

Analyses were conducted on completers, that is, those who attended both the baseline and six month clinical visits. Restricting analyses to completers, as opposed to using last observation carried forward (LOCF) when data is missing, is justified given the objectives of this investigation. What is of interest in this investigation is change in expenses among active participants in the intervention, not whether the intervention can elicit change across an

experimental group. To investigate change in study sub groups, results were stratified by demographic (age and gender) and goal attainment (weight loss, activity) variables. Grocery and non-grocery store food expenses were combined into a Store Food category, reflecting changes in the grocery business since the Flexible Consumer Behavior Questionnaire was developed as stores like WalMart and Costco are now major food retailers, yet not considered grocery stores by earlier definitions. The six-month food expenses were adjusted for inflation using Consumer Price Index data (<http://www.bls.gov/cpi/cpid1301.pdf>) and are presented as adjusted and unadjusted values.

The Wilcoxon Signed-Rank Sum test was used to test the change of expenses within the two study groups from baseline to clinical visits, and the Wilcoxon Rank Sum test evaluated change between the immediate and control groups. The Spearman Rank-Order Correlation test was used to test correlations between variables. Analyses were carried out using the SAS statistical package (version 9.3, SAS Institute, Cary North Carolina, USA).

## **Results**

The three community centers from which participants were recruited were located diverse socioeconomic communities. While all three centers had large retiree populations, economically and educationally they ranged from being composed of primarily blue collar to having a significant proportion of participants with graduate degrees.

Interested individuals received telephone or in-person preliminary screening, identifying 204 potentially eligible individuals, of whom 154 were confirmed eligible by clinical screening. Of these, 134 participants provided informed consent. 88 participants were randomized to the immediate intervention group and 46 to the delayed intervention control. At baseline, there were

no significant differences in clinical or demographic values between the immediate intervention and delayed control groups (Table C.1).

**Table C.1 Participant Baseline Characteristics**

<b>Variable</b>	<b>Intervention Mean (sd) Median (IQR) (n=88)</b>	<b>Control Mean (sd) Median (IQR) (n=46)</b>	<b>p-between groups</b>
<b>Weight (lbs)</b>	212.4 (46.3) 202.3 (181.3-241.5)	201.5 (37.1) 195.1 (176.8-220.4)	.17
<b>Glucose (mg/dl)</b>	96.0 (10.3) 94.0 (89-101)	95.9 (13.1) 93.0 (87-102)	.94
<b>HbA1C (%)</b>	5.80 (0.32) 5.7 (5.6-5.9)	5.76 (0.33) 5.7 (5.6-5.9)	.53
<b>Gender (% female, n)</b>	65.9% (58)	69.6% (32)	.67
<b>Age (average years, range)</b>	62.8 (12.1)	61.9 (11.9)	.66
<b>Usual number of people in household</b>	2.02 (0.98) 2.0 (1-2)	1.78 (0.66) 2.0 (1-2)	.32

During the first six months of the intervention, weight decreased significantly (-5.1%,  $p<0.001$ ) from baseline in the immediate intervention group, and was significantly decreased relative to the control group ( $p<0.001$ ). Additionally, glucose, HbA1c, and waist circumference were significantly reduced at six months from baseline in the intervention group and when compared with the control, similar to what was reported in previous GLB interventions [2,20,21]. The median weekly minutes of self-reported physical activity in the intervention group significantly increased from baseline at six months (180 to 210,  $p=0.02$ ) and this change was significantly greater than the control group ( $p=0.05$ ). This resulted in the intervention group

reporting nearly double the weekly physical activity time of the control group (210 minutes to 112.5).

At the six-month clinical assessment there were no significant changes in reported food expenses in all food categories for participants in the immediate intervention group (store food, take-out food, eating-out food, total food) when compared to baseline. Interestingly, in the delayed control group there was a significant increase in estimated total monthly food spending from \$594 to \$674 ( $p=0.04$ ) over this same time period (Table C.2). There was a significant difference in the change between the control and intervention groups in the amount of money spent eating at restaurants, cafeterias, and buffets, due to the fact that expenses in the control group increased while the intervention group expenses decreased (Table C.2). No other changes comparisons between food purchase groups were significant. Adjusting food expenses data for food price inflation weakened the significance of the finding regarding eating out expenses between the control and intervention groups. Other food expenses results were unchanged after inflation adjustment (Appendix C1).

There were no significant differences in the change of total food expenses in the intervention group when stratified by achievement of weight loss goals (any,  $\geq 5\%$  and  $\geq 7\%$  of baseline body weight) or education as a proxy for socioeconomic status (data not shown). These reported expenses are household-level, and thus only indicate the expenses of an individual GLB participant when household size=1. Stratifying by a household size of one compared to more than one also resulted in no significant changes from baseline or between groups for total food expenses or any of the component categories (data not shown).



**Table C.2 Food Expenses by Purchase Site, Comparing Delayed and Immediate Groups Over Six Months of Intervention.**

Estimates of average monthly food purchase amounts per month over last 6 months	Delayed Group baseline I Mean (sd) Median (IQR) n=31	Delayed Group baseline II Mean (sd) Median (IQR) n=31	Delayed Group Baseline I to II Change Mean (sd) Median (IQR) n=31	p	Immediate Group baseline Mean (sd) Median (IQR) n=60	Immediate Group 6 MO Mean (sd) Median (IQR) n=60	Baseline to 6 MO Change Mean (sd) Median (IQR) n=60	p	p-between groups
<b>Store food (grocery and non-grocery, (\$/household))</b>	364.68 (182.57) 360 (240-430)	455.10 (255.10) 400 (260-625)	90.42 (226.86) 25 (-40-150)	0.08	423.88 (300.14) 385 (200-575)	469.65 (351.00) 400 (222.5-580)	45.77 (323.82) 40 (-75-100)	0.21	.45
<b>Purchased take-out food % (n)</b>	51.6% (16)	41.9% (13)	-9.7% (-3)	0.61	70.0% (42)	55.0% (33)	-15.0% (-9)	0.13	
<b>Take-out food per month (\$/household)</b>	54.94 (143.58) 10 (0-60)	25.65 (39.00) 0 (0-50)	-29.29 (147.84) 0 (-30-12)	0.35	36.15 (43.08) 24.50 (0-55)	30.62 (45.53) 6.50 (0-50)	-5.53 (43.44 ) 0 (-19-0)	0.13	.82
<b>Purchased eat-out % (n)</b>	31	31	0% (0)	1.0	91.6% (55)	85.0% (51)	-6.0%	0.39	
<b>Eating out food per month (\$/household)</b>	174.74 (184.28) 132 (75-210)	193.55 (138.94) 150 (100-240)	18.81 (160.11) 20 (-30-80)	0.13	115.08 (115.35) 80 (25-175)	101.87 (97.37) 100 (25-155)	-13.22 (78.98) 0 (-40-20)	0.25	<b>.045</b>
<b>Total of estimated food spending per month (\$)</b>	594.35 (434.84) 525 (420-665)	674.29 (319.91) 635 (430-785)	79.94 (418.19) 90 (-65-270)	<b>0.04</b>	575.12 (377.21) 497.5 (275-780)	602.13 (400.77) 528 (330-793.5)	27.02 (371.14) 17 (-91.5-107.5)	0.62	.14

For total expenses related to participating in physical activity, the change in the intervention group was of borderline significance (\$245 to \$180,  $p=0.06$ ) (Table C.3), resulting from a significant decrease in expenses for physical activity services (\$189 to \$134,  $p=0.03$ ). When stratifying by gender, there was a significant decline in expenses for physical activity from baseline to six months in men (\$196 to \$103,  $p=0.05$ ) but not women. Although participants aged less than 60 had higher expenses related to physical activity than those aged 60 or over, change in activity expenses was not different when stratified by age (data not shown). There were no significant correlations between physical activity expenses or change in physical activity expenses and the monthly frequency or change of frequency of activities reported on the MAQ (data not shown).

In terms of time, not surprisingly, participants in the immediate intervention group significantly increased the time they put into self-monitoring over six months, relative to baseline and when compared to the control group. This result was unchanged when stratified by gender or age (data not shown).

**Table C3. Expenses Related to Physical Activity.**

Household Activity Expense Categories (\$/6 months)	Control Baseline Mean (sd) Median (IQR) n=42	Control 6 Months Mean (sd) Median (IQR) n=42	Control Change Mean (sd) Median (IQR) n=42	p	Intervention Baseline Mean (sd) Median (IQR) n=81	Intervention 6 Months Mean (sd) Median (IQR) n=81	Intervention Change Mean (sd) Median (IQR) n=81	p	p-between groups
<b>Items (ex. shoes, clothing, bike)</b>	38.88 (55.14) 0 (0-65)	87.81 (174.92) 39.50 (0-100)	48.93 (165.98) 0 (-25-100)	.06	56.67 (127.55) 0 (0-75)	46.12 (65.41) 0 (0-83)	-10.54 (112.31) 0 (-34-10)	.40	.10
<b>Services (ex. classes, gym membership)</b>	161.21 (295.06) 0 (0-210)	92.82 (158.00) 0 (0-192)	-68.39 (239.88) 0 (-50-0)	.09	188.93 (512.91) 0 (0-192)	134.07 (382.29) 0 (0-100)	-54.85 (409.76 ) 0 (-25-0)	<b>.03</b>	.86
<b>Total</b>	200.10 (300.01) 96 (0-285)	180.63 (222.21) 95 (0-300)	-19.47 (279.75) 0 (-55-100)	1.0	245.59 (535.48) 75 (0-270)	180.20 (387.33) 60 (0-199)	-65.40 (421.76) 0 (-76-20)	.06	.51

## Discussion

The results from this investigation suggest that at-risk participants in a translational type 2 diabetes prevention intervention delivered in the community can successfully reduce their diabetes risk factors without substantial increases in direct out-of-pocket nonmedical expenses for food or to facilitate physical activity. The only significant increase in expenses in the intervention group relative to the control group was related to the time involved in self-monitoring.

These findings build on earlier reports from the DPP clinical trial [12] which suggested little change in direct nonmedical expenses in the intervention group, relative to the control. They are also consistent with the HELP-PD results [13], but take their results one step further and demonstrate that these findings are statistically significant.

Among some unanticipated results: Total estimated food expenses increased in the control group during the six months between baseline and start of the intervention. It is possible that, in anticipation of future deprivation these participants purchased (and ate) more than they otherwise would have [22]. Alternatively, these participants might have attempted to improve their diet by increasing purchases of more expensive food items that they considered healthy, in an attempt to jump-start healthier lifestyle changes. Seasonal factors probably contribute to two further unanticipated findings in both the intervention and control groups. The decrease in expenses for activity services was significant in the intervention group and borderline in the controls. As the baseline assessment visit was in February and March, expenses reported for the previous six months included late fall and early winter months when opportunities for outdoor physical activity are more limited and gym memberships increase. It is likely that decreased indoor physical activity during the spring and summer months at gyms and fitness centers

accounts for the decrease in physical activity service expenses from the baseline to the August and September six month assessment. The decrease in time spent cooking in both groups over may also be due to seasonal factors that favor meals with less preparation time during the warmer months of the year.

For time spent in self-monitoring, the increases in the intervention group from baseline and relative to the control reflect the impact of the GLB lifestyle intervention, which encourages self-monitoring as a tool to assist in meeting physical activity, calorie, and weight loss goals. It should be noted that while average physical activity time significantly increased in both the intervention and control groups, the median decreased and the IQR increased in the control group and the median increased and IQR decreased in the intervention group. This suggests that the GLB lifestyle intervention may have been successful in increasing physical activity among the intervention group as a whole, while in the delayed group, the mean activity time increase was due to substantial activity increases in a smaller number of highly motivated individuals.

These findings are limited by data that are self-reported and may not reflect actual purchases and individual consumption. They are additionally subject to seasonal influences during the six-month period that may confound both the control and intervention groups. Starting a future intervention in the late summer or fall would control for possible seasonal factors observed here.

In summary, these findings indicate that, as part of a behavior lifestyle intervention, statistically significant and clinically meaningful reductions in type 2 diabetes risk factors can be achieved in the absence of significant increases in expenses, beyond the time involved in self-monitoring. It is likely that in a given household, economic decisions are made within the financial constraints of the household, and that minimally increased or cost-neutral food and

activity choices can be identified by committed participants, working with their lifestyle coaches. Such findings should help make participation in a diabetes prevention intervention program more attractive for those at elevated risk who might view increased costs an obstacle to successful program participation.

## Appendix C.1

**Table C.4 Inflation adjusted food expenses by purchase site, comparing delayed and immediate groups over six months of intervention. Constant 1<sup>st</sup> half 2012 dollars. (Source: <http://www.bls.gov/cpi/#tables>) Jan 2013 data for Pittsburgh, PA. Inflation factors: food at home 0.9% applied to store and take-out food; food away from home 0.7% applied to eating-out food.**

Estimates of average monthly food purchase amounts per month over last 6 months	Delayed Group baseline I Mean (sd) Median (IQR) n=31	Inflation Adjusted Delayed Group baseline II Mean (sd) Median (IQR) n=31	Delayed Group Baseline I to II Change Mean (sd) Median (IQR) n=31	p	Immediate Group baseline Mean (sd) Median (IQR) n=60	Inflation Adjusted Immediate Group 6 MO Mean (sd) Median (IQR) n=60	Baseline to 6 MO Change Mean (sd) Median (IQR) n=60	p	p-between groups
<b>Store food (grocery and non-grocery, (\$/household)</b>	364.68 (182.57) 360 (240-430)	451.04 (252.83) 396.43 (258-619)	86.36 (225.23) 19.43 (-44-147)	0.11	423.88 (300.14) 385 (200-575)	465.46 (347.87) 396.43 (221-575)	41.58 (321.93) 37.23 (-78-98)	0.24	.47
<b>Take-out food per month (\$/household)</b>	54.94 (143.58) 10 (0-60)	25.42 (38.66) 0 (0-50)	-29.52 (147.76) 0 (-30-11)	0.27	36.15 (43.08) 24.50 (0-55)	30.34 (45.12) 6.44 (0-50)	-5.81 (43.23 ) -0.29 (-19-0)	0.07	.72
<b>Eating out food per month (\$/household)</b>	174.74 (184.28) 132 (75-210)	192.20 (137.97) 148.96 (99-238)	17.46 (159.87) 19.30 (-30-78)	0.19	115.08 (115.35) 80 (25-175)	101.16 (96.69) 99.30 (25-154)	-13.92 (78.88) -0.70 (-41-19)	0.21	.058
<b>Total of estimated food spending per month (\$)</b>	594.35 (434.84) 525 (420-665)	668.66 (317.20) 629.57 (426-778)	74.30 (417.23) 84.11 (-70-260)	<b>0.05</b>	575.12 (377.21) 497.5 (275-780)	596.96 (397.28) 523.41 (327-787)	21.84 (369.28) 14.08 (-97-103)	0.65	.14

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## APPENDIX D: PARTICIPANT EXPENSE SURVEY-6 MONTH ASSESSMENT

We are asking you to complete this survey so that we can learn more about the time and expenses related to taking part in a healthy lifestyle change program. This survey asks questions about your time and expenses for attending group sessions and/or following the DVD sessions (depending on your choice of program delivery), the time that you spent in physical activity related activities, and the time you spent in tracking your progress. This survey also asks about specific food and exercise items purchased, health care use, and employment.

Most questions in the survey refer to a specific time period. The most common time period for the responses is the last **6 months**.

Please complete as much of this survey as possible before your upcoming visit. The DPSC staff will review the survey with you when you come for your visit. If you have questions regarding the survey, you may ask them at your visit during the survey review, or please feel free to call the DPSC at 412-383-1286.

### Intervention-Related Time and Expenses:

Considering what you did in the last **6 months**, and thinking about your involvement with the study...

1. What method of travel do you primarily use to get to the GLB group sessions? (**Check one**)

- ☐ <sub>1</sub> Your own family car (please also answer questions 2 and 3)
- ☐ <sub>2</sub> A friend's car (please also answer questions 2 and 3)
- ☐ <sub>3</sub> Bus (skip to question 4)
- ☐ <sub>4</sub> Train (skip to question 4)
- ☐ <sub>5</sub> Taxi (skip to question 4)
- ☐ <sub>6</sub> Walk (skip to question 4)

☐ 7

Other (specify: \_\_\_\_\_)

☐ 8

Have not attended group sessions in the last 6 months (skip to question 8)

2. If you drove or were driven to the group session site, about how many miles did you travel round trip? [for one session]

\_\_\_\_\_ miles

3. Did you have any parking expenses? ☐ 1 Yes ☐ 2 No ☐ 3 Doesn't apply
- a. If yes, what were your expenses? [consider the total for all visits in the last 4 or 6 months]

\$ \_\_\_\_\_

4. If you used a travel method other than your own or a friend's car, what was the estimated travel cost for you for a typical round trip visit to the group session site?

\$ \_\_\_\_\_

☐ 1 Walked, doesn't apply

5. What is the estimated average round trip travel time to the group session site? \_\_\_\_\_

6. What would you be doing if you were not traveling to and attending the GLB group session?  
**(Check all that apply)**

- a. ☐ 1 Work at a job outside the home
- b. ☐ 1 Household activities *(including cleaning, mowing the lawn, making home repairs, and other activities needed to keep the household running)*
- c. ☐ 1 Going to school
- d. ☐ 1 Leisure activities *(including exercise, hobbies, resting, reading, watching television, eating a meal)*
- e. ☐ 1 Other (specify): \_\_\_\_\_)

7. If you missed work in order to attend the sessions, did you lose any earnings in your wage or salary because of your attendance?

☐ <sub>1</sub> Yes    ☐ <sub>2</sub> No    ☐ <sub>3</sub> Doesn't apply

a. If yes, about how much earnings/wage did you lose? [consider the total for all visits in the last 6 months]

\$ \_\_\_\_\_

8. What was the estimated average amount of time that you spent in viewing the GLB DVDs in a typical week?

:    
hours                  minutes

☐ <sub>1</sub> Did not watch any GLB-DVD's (skip to question 11)

9. What would you be doing if you were not viewing the GLB DVDs?

**(Check all that apply)**

a. ☐ <sub>1</sub> Work at a job outside the home

b. ☐ <sub>1</sub> Household activities (*including cleaning, mowing the lawn, making home repairs, and other activities needed to keep the household running*)

c. ☐ <sub>1</sub> Going to school

d. ☐ <sub>1</sub> Leisure activities (*including exercise, hobbies, resting, reading, watching television, eating a meal*)

e. ☐ <sub>1</sub> Other (specify): \_\_\_\_\_)

10. If you missed work in order to view the DVDs, did you lose any earnings in your wage or salary because of this action?

☐ <sub>1</sub> Yes    ☐ <sub>2</sub> No    ☐ <sub>3</sub> Doesn't apply

a. If yes, about how much earnings/wage did you lose? [consider the total for the last 6 months]

\$ \_\_\_\_\_

## Time Recording Self-Monitoring Activities

*The following questions ask about your usual patterns in tracking your physical activity and eating. We are interested in the time that you spent recording your eating and physical activity.*

*The next two questions ask you to think about this involvement in a typical week over the **first 3 months** of the GLB program.*

11. In the first **3 months** of the GLB program, on average in a **typical week**, about how much time did you spend recording your physical activity levels in a diary or log?

<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>
hours			minutes	

12. In the first **3 months** of the GLB program, on average in a **typical week**, about how much time did you spend recording your eating and beverage intake in a diary or log?

<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>
hours			minutes	

*The next two questions ask you to think about this involvement in a typical week over the **most recent 3 months** of the GLB program.*

13. In **months 3-6** of the GLB program, on average in a **typical week**, about how much time did you spend recording your physical activity levels in a diary or log?

<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>
hours			minutes	

14. In **months 3-6** of the GLB program, on average in a **typical week**, about how much time did you spend recording your eating and beverage intake in a diary or log?

<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>
hours			minutes	

### Time in Exercise

The next questions ask about your usual involvement in physical activity. Please think about this involvement in a typical week over the last **6 months**.

15. On average in a **typical week**, about how much time did you spend in physical activity?

:   
hours minutes

→ If none, skip to question 17.

16. What would you otherwise have been doing if you were not in physical activity? (**Check all that apply**)

- a. ☐ Work at a job outside the home
- b. ☐ Other forms of leisure that do not involve physical activity
- c. ☐ Household work
- d. ☐ Other (specify: \_\_\_\_\_)

### Time in Food Preparation

Next, please consider the time related to food preparation for the household where you live. Please think about this involvement in a typical week over the last **6 months**.

17. Regarding your eating habits:

- a. During a typical week, how many times did you or someone else in your family prepare or cook food for dinner or supper at home?

times or ☐ Don't know

- b. About how much time did the person(s) doing most of the cooking for the household spend per week on cooking dinner or supper and cleaning up after the cooking? (Please do not include time spent eating)

:  or ☐ Don't know  
hours minutes

### Physical Activity Expenses

*Next, please consider any expenses that you incurred related to physical activity over the last **6 months**.*

18. Over the last **6 months**, did you purchase any exercise shoes (walking, running, or sport-specific shoes)?

☐ <sub>1</sub> Yes    ☐ <sub>2</sub> No    ☐ <sub>3</sub> Don't know

**If YES,**

a. How many pairs of shoes were purchased?

pairs

b. What was the total cost of the shoes purchased? (round to nearest \$)

\$    **or** ☐ <sub>1</sub> Don't know

19. Over the last **6 months**, have any of the following items been purchased to help in your physical activity? (This may include equipment and clothing.)

☐ <sub>1</sub> Yes

☐ <sub>2</sub> No

**If Yes, what did it cost?** (round to nearest \$).

- |                                |   |  |  |  |
|--------------------------------|---|--|--|--|
| a. Exercise videos             | <input type="checkbox"/> <sub>1</sub> Yes | <input type="checkbox"/> <sub>2</sub> No | <input type="checkbox"/> <sub>3</sub> Don't know | \$ <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> |
| b. Free weights (dumbbells)    | <input type="checkbox"/> <sub>1</sub> Yes | <input type="checkbox"/> <sub>2</sub> No | <input type="checkbox"/> <sub>3</sub> Don't know | \$ <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> |
| c. Clothing for exercise       | <input type="checkbox"/> <sub>1</sub> Yes | <input type="checkbox"/> <sub>2</sub> No | <input type="checkbox"/> <sub>3</sub> Don't know | \$ <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> |
| d. Stationary bicycle          | <input type="checkbox"/> <sub>1</sub> Yes | <input type="checkbox"/> <sub>2</sub> No | <input type="checkbox"/> <sub>3</sub> Don't know | \$ <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> |
| e. Regular bicycle             | <input type="checkbox"/> <sub>1</sub> Yes | <input type="checkbox"/> <sub>2</sub> No | <input type="checkbox"/> <sub>3</sub> Don't know | \$ <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> |
| f. Treadmill                   | <input type="checkbox"/> <sub>1</sub> Yes | <input type="checkbox"/> <sub>2</sub> No | <input type="checkbox"/> <sub>3</sub> Don't know | \$ <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> |
| g. Elliptical machine          | <input type="checkbox"/> <sub>1</sub> Yes | <input type="checkbox"/> <sub>2</sub> No | <input type="checkbox"/> <sub>3</sub> Don't know | \$ <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> |
| h. Swimming trunks or swimsuit | <input type="checkbox"/> <sub>1</sub> Yes | <input type="checkbox"/> <sub>2</sub> No | <input type="checkbox"/> <sub>3</sub> Don't know | \$ <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> |
| i. Other (specify): _____      | <input type="checkbox"/> <sub>1</sub> Yes | <input type="checkbox"/> <sub>2</sub> No | <input type="checkbox"/> <sub>3</sub> Don't know | \$ <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> |

20. Over the last **6 months**, were any of the following services purchased to help you in your physical activities?

☐ <sub>1</sub> Yes

☐ <sub>2</sub> No

**If YES, what was the total cost paid in this 6 month period for this service** (include items like initiation fees, monthly dues, locker fees, towel fees, etc.)? (round to nearest \$)

- |                                    |   |  |  |  |
|------------------------------------|---|--|--|--|
| a. Exercise or aerobics classes    | <input type="checkbox"/> <sub>1</sub> Yes | <input type="checkbox"/> <sub>2</sub> No | <input type="checkbox"/> <sub>3</sub> Don't know | \$ <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> |
| b. Health club or gym membership   | <input type="checkbox"/> <sub>1</sub> Yes | <input type="checkbox"/> <sub>2</sub> No | <input type="checkbox"/> <sub>3</sub> Don't know | \$ <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> |
| c. Other exercise related services | <input type="checkbox"/> <sub>1</sub> Yes | <input type="checkbox"/> <sub>2</sub> No | <input type="checkbox"/> <sub>3</sub> Don't know | \$ <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> |



## Food Expenses

The next questions are about how much money your family spends on food. Food expenses may come from several places. First, we will ask you about money spent on food at supermarkets or grocery stores. Then, we will ask about money spent at other types of stores where you buy food. Lastly, we will ask about prepared food that you carry home or have delivered to your home and money that you spend on eating out in restaurants. Consider your typical experience **in the last 6 month period** when answering the questions.

21. During the last **6 months**, how much money did your family spend per week or per month at supermarkets or grocery stores? Include purchases made with food stamps. (round to nearest \$) (you may answer either as weekly or monthly costs, whichever is easier for you to recall)

\$  per week or \$  per month or  <sub>1</sub> Don't know

- a. Was any of this money spent on nonfood items such as cleaning or paper products, pet food, cigarettes, or alcoholic beverages?

<sub>1</sub> Yes  <sub>2</sub> No  <sub>3</sub> Don't know

- b. About how much of this amount, if any, was for non-food items, such as cleaning or paper products, food bought for feeding a pet, or cigarettes? (IF NONE, ENTER "0") (you may answer either as weekly or monthly costs, whichever is easier for you to recall)

\$  per week or \$  per month or  <sub>1</sub> Don't know

Think now of shopping done in different types of places (not grocery stores) that sell food.

22. During the last **6 months**, did your family spend money on food at stores other than grocery stores (such as bakeries, delicatessens, meat markets, wholesale stores (Costco, Sam's), vegetable stands, farmer's markets, health food stores, convenience stores, Target, Wal-Mart, Kmart, and other similar places)? Please do not include stores that you have already told us about)

<sub>1</sub> Yes  <sub>2</sub> No  <sub>3</sub> Don't know

23. During the last **6 months**, about how much did your family spend on food at these types of stores per week or per month ? (**IF NONE, ENTER "0".**) (round to nearest \$) (you may answer **either** as weekly or monthly costs, whichever is easier for you to recall)

\$  per week or \$  per month or  <sub>1</sub> Don't know

- a. Does the household regularly get food or food commodities from a food bank or other source?  <sub>1</sub> Yes  <sub>2</sub> No  <sub>3</sub> Don't Know

*Think now of prepared food that was purchased outside of the home, but carried home to eat. This also includes prepared food delivered to your home.*

24. During the last **6 months**, how much did your family spend per week or per month on food carried out or delivered to your home? (please do not include money that you have told us about already) **(IF NONE, ENTER "0")** (round to nearest \$) (you may answer **either** as weekly or monthly costs, whichever is easier for you to recall)

\$  per week or \$  per month or <sub>1</sub> Don't know

*Think now of food purchased and eaten away from your home.*

25. During the last **6 months**, how much money did your family spend per week or per month on **eating out**? Please include money spent in restaurants, fast food places, cafeterias at work or at school, or purchased from vending machines, for all family members. **(IF NONE, ENTER "0".)** (round to nearest \$) (you may answer **either** as weekly or monthly costs, whichever is easier for you to recall)

\$  per week or \$  per month or <sub>1</sub> Don't know

*Now, think of your total food purchases from all sources, regardless of where eaten, including restaurants.*

26. During the last **6 months**, compared to your experience before the intervention, would you say that you spend more, spend less, or spend about the same amount of money on food?

<sub>1</sub> Spend more on food    <sub>2</sub> Spend less on food    <sub>3</sub> Spend the same on food

*Finally, think of the usual size (number of persons) in your family or household, for which you reported the food expenses above.*

27. During the last **6 months**, what was the usual number of persons in your family or household who were consumers of the food purchases reported here?

\_\_\_\_\_ (# of persons)

## Medical Issues

*Next, please consider any health events that have occurred over the last **6 months** and your use of health services for those events.*

28. In the last **6 months**, were you injured as a result of your participation in physical activity?

☐ <sub>1</sub> Yes    ☐ <sub>2</sub> No    ☐ <sub>3</sub> Don't know    **(If no, skip to question 29)**

If yes, briefly describe the type of injury and when/how/where it occurred

---

a. If yes, did you receive any care from the following:

- Hospital requiring an overnight stay?    ☐ <sub>1</sub> Yes    ☐ <sub>2</sub> No    ☐ <sub>3</sub> Don't know

If yes, how many nights were you hospitalized? \_\_\_\_\_

- Hospital emergency room?    ☐ <sub>1</sub> Yes    ☐ <sub>2</sub> No    ☐ <sub>3</sub> Don't know

- A doctor seen in his/her office?    ☐ <sub>1</sub> Yes    ☐ <sub>2</sub> No    ☐ <sub>3</sub> Don't know

If yes, how many visits to this doctor did you have? \_\_\_\_\_

b. If yes, did you receive any prescription medicines for the treatment of the injury?

☐ <sub>1</sub> Yes    ☐ <sub>2</sub> No    ☐ <sub>3</sub> Don't know

If yes, what were you treated with? \_\_\_\_\_

c. If yes, did you use any non-prescription medicines or devices (bandages) for the treatment of the injury?    ☐ <sub>1</sub> Yes    ☐ <sub>2</sub> No    ☐ <sub>3</sub> Don't know

If yes, what did you use? \_\_\_\_\_

29. In the last **6 months**, were you diagnosed with diabetes or told by a doctor that you have diabetes? ☐ <sub>1</sub> Yes ☐ <sub>2</sub> No ☐ <sub>3</sub> Don't know **(If no, skip to question 30)**

a. If yes, did you receive any care from the following:

- Hospital requiring an overnight stay? ☐ <sub>1</sub> Yes ☐ <sub>2</sub> No ☐ <sub>3</sub> Don't know

If yes, how many nights were you hospitalized? \_\_\_\_\_

- Hospital emergency room? ☐ <sub>1</sub> Yes ☐ <sub>2</sub> No ☐ <sub>3</sub> Don't know

- A doctor seen in his/her office? ☐ <sub>1</sub> Yes ☐ <sub>2</sub> No ☐ <sub>3</sub> Don't know

If yes, how many visits to this doctor did you have? \_\_\_\_\_

b. If yes, did you receive any prescription medicines for treatment of diabetes?

☐ <sub>1</sub> Yes ☐ <sub>2</sub> No ☐ <sub>3</sub> Don't know

If yes, what were you treated with? \_\_\_\_\_

30. In the last **6 months**, has your health changed in any notable way? For example, you may feel that your health has improved or worsened.

☐ <sub>1</sub> Yes, my health has improved ☐ <sub>1</sub> No, my health has not changed

☐ <sub>1</sub> Yes, my health has worsened ☐ <sub>1</sub> Don't Know

31. In the last **6 months**, did you receive any care from the following: (do not include the visits that you told us about already)

- Hospital requiring an overnight stay? ☐ <sub>1</sub> Yes ☐ <sub>2</sub> No ☐ <sub>3</sub> Don't know

If yes, how many nights were you hospitalized? \_\_\_\_\_

- Hospital emergency room? ☐ <sub>1</sub> Yes ☐ <sub>2</sub> No ☐ <sub>3</sub> Don't know

- A doctor seen in his/her office? ☐ <sub>1</sub> Yes ☐ <sub>2</sub> No ☐ <sub>3</sub> Don't know

If yes, how many visits to this doctor did you have? \_\_\_\_\_

- Any prescription medicines? ☐ <sub>1</sub> Yes ☐ <sub>2</sub> No ☐ <sub>3</sub> Don't know

If yes, what were you treated with? \_\_\_\_\_

## Absenteeism

*Finally, please consider your work patterns over the last **6 months**.*

32. In the last 6 months, were you working either full or part time? ☐ <sub>1</sub> Yes ☐ <sub>2</sub> No

**If no, your survey is complete and no further responses are necessary**

33. About how many hours altogether did you work in the last 7 days?   hours

34. On average, how many hours does your employer expect you to work in a typical 7 day week?   hours

35. Now please think of your work experiences over the last 4 weeks (28 days). In the questions below, write the number of days that you spent in each of the following work situations.....

**In the last 4 weeks, how many days did you....**

- |   |  |
|---|--|
| a. miss an <b>entire</b> work day because of problems with your physical or mental health? (please include only days missed for your own health, not someone else's health) | <input type="text"/> <input type="text"/> days |
| b. miss an <b>entire</b> work day for any other reason (including vacation)?  | <input type="text"/> <input type="text"/> days |
| c. miss <b>part</b> of a work day because of problems with your physical or mental health? (please include only days missed for your own health, not someone else's health) | <input type="text"/> <input type="text"/> days |
| d. miss <b>part</b> of a work day for any other reason (including vacation)?  | <input type="text"/> <input type="text"/> days |
| e. Come in early, go home late, or work on your day off?  | <input type="text"/> <input type="text"/> days |

36. About how many hours altogether did you work in the **last 4 weeks** (28 days)? (See examples below.)

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hours

Number of hours in the last 4 weeks (28 days)

### Examples for Calculating Hours Worked in the Last 4 Weeks

40 hours per week for 4 weeks = 160 hours  
 35 hours per week for 4 weeks = 140 hours  
 40 hours per week for 4 weeks with 2 8-hour days missed = 144 hours  
 40 hours per week for 4 weeks with 3 4-hour partial days missed = 148 hours  
 35 hours per week for 4 weeks with 2 8-hour days missed  
 and 3 4-hour partial days missed = 112 hours

37. On a scale from 0 to 10 where 0 is the worst job performance anyone could have at your job and 10 is the performance of a top worker, how would you rate the usual performance of **most** workers in a job similar to yours? (circle the number)

<i>Worst</i>												<i>Top</i>
<i>Performance</i>												<i>Performance</i>
	0	1	2	3	4	5	6	7	8	9	10	

38. Using the same 0 to 10 scale, how would you rate your **usual** job performance over the last year or two?

<i>Worst</i>												<i>Top</i>
<i>Performance</i>												<i>Performance</i>
	0	1	2	3	4	5	6	7	8	9	10	

39. Using the same 0 to 10 scale, how would you rate your **overall** job performance on the days you worked during the **last 4 weeks** (28 days)?

<i>Worst</i>												<i>Top</i>
<i>Performance</i>												<i>Performance</i>
	0	1	2	3	4	5	6	7	8	9	10	

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